HIT Standards Committee Meeting
Final Transcript
April 28, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody, and welcome to the 12th meeting of the HIT Standards Committee. This is a federal advisory committee, which means there will be opportunity at the end of the meeting for the public to make comment, and we will have the summary and minutes of the meeting posted on the Web site within about a week. Just a reminder for committee members to please identify yourselves when speaking so audience listening on the Web and on the phone can identify who is speaking. And let me ask you to go around the room and introduce yourselves briefly, beginning on my right with Cris Ross.

Cris Ross – MinuteClinic – CIO
Good morning. Cris Ross, CVS MinuteClinic.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
David McCallie, Cerner.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Liz Johnson, Tenet Healthcare.

Martin Harris – Cleveland Clinic – Chief Information Officer
Martin Harris, Cleveland Clinic.

Janet Corrigan – National Quality Forum – President & CEO
Janet Corrigan, NQF.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
Anne Castro, BlueCross BlueShield South Carolina.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
John Derr, Golden Living.

Kevin Hutchinson – Prematics, Inc. – CEO
Kevin Hutchinson, Prematics.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Carol Diamond, Markle.

John Halamka – Harvard Medical School – Chief Information Officer
John Halamka, Harvard Medical School.

Jonathan Perlin – Hospital Corporation of America – CMO & President
John Perlin, HCA Healthcare.

David Blumenthal – Department of HHS – National Coordinator for Health IT

David Blumenthal, Office of the National Coordinator.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Dixie Baker, Science Applications International.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Jamie Ferguson, Kaiser Permanente.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Chris Chute, Mayo Clinic.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst
Steve Findlay, Consumers Union.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Judy Murphy, Aurora Healthcare.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Wes Rishel, Gartner.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Jim Walker, Geisinger Health System.

Judy Sparrow – Office of the National Coordinator – Executive Director
On the phone, I believe we have John Klimek. Are you there, John?

John Klimek – NCPDP – VP Industry Information Technology
Yes, I am.

Judy Sparrow – Office of the National Coordinator – Executive Director
And any other member on the telephone?

Sharon Terry – Genetic Alliance – President & CEO
Yes. Sharon Terry, Genetic Alliance.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thanks, Sharon. All right. With that, I'll turn it over to Dr. Blumenthal for opening remarks.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Very brief welcome, both to those who are present here and to our listeners on the phone and participants on the phone. We are working hard at the Office of the National Coordinator to respond to the many useful comments we've gotten from the public and from this group about our interim final rule on standards and certification criteria and on the certification process. We hope, as we've said before, to have those final rules ready to go this spring.

We also will be talking later about how no good deed goes unpunished. You all have done such good work that Congress has given you some additional work that you may not have been aware of through the Health Reform Law. Your chair and cochair will be discussing that in more detail. But for those of you who have the bill instantly at your disposal, it's Section 1561 of the law entitled *Health Information Technology Enrollment Standards and Protocols*, and it directs us to work with you to take our work in a

rather different direction, but an important one for the realization of the aspirations of health reform. I'll end my remarks there and let you fanaticize for a little while about what I could have in mind. But you won't have to wait long to get the answer.

In any case, we continue to work. As much as we accomplish, we find additional challenges on the horizon, and the horizon isn't that far away. For us, horizons can be weeks rather than months or years, and so we are working also on thinking about further the Nationwide Health Information Network, which Doug Fridsma continues to lead the work on. The governance of the NHIN, which is something we are tasked with thinking about as part of the HITECH legislation, and continue to now work much more intensively on the implementation of our grant programs going forward, as well as preparing for working with the physician and hospital, nursing and clinician community generally once meaningful use is finally defined, at least for this interim period until we revise it in a later stage.

No lack of things to do. We continue to depend on you, and hope that you can see the evidence of your work and advice in decisions that we are making through the rulemaking process. With that, I won't extend the conversation anymore and turn the podium and microphone over to John Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, David. Thanks to the always hard work and great work and leadership of ONC, and many thanks to all the members of the committee and the public for terrific and continuing input into the process. I particularly appreciate the very tantalizing introduction because, indeed, it feels like a full circle, and I think this is a meeting where our work begins to take a slightly different direction. That is to say that we've been operating within the framework where things have to come together, but indeed we've been operating a somewhat molecular, even sort of atomic level.

The question, of course, is how do these things come together, and our work on the implementation workgroup, in fact, through some of the elements you mentioned in terms of the broader topic of health reform and NHIN, for example, begin to really objectify the need and discussion of the interation of the different elements, the vocabulary and transaction standards that clinical operations have been working on with the work, obviously, of clinical quality and privacy and security and so the implementation begins to take distinctly practical bends, which is something, I think, many of us here have been very sensitive to. Not to say it's been impractical, but it's hard to have the conversation about how things come together until you define some of the component pieces. I appreciate seeing some of the heads nod that that's the discussion that you've been looking forward to. Indeed, that tees up a body of work.

One note on the agenda, toward that end, after Cris provides some comments on the work of the implementation, we've asked Doug Fridsma to come back and begin to give some structure to that conversation about how things begin to come together and to just sort of think, as we review the materials that have been prepared, how we orient towards the next set of activities. Let me, as well, stop there. We'll come back after John Halamka's comments for the discussion of approval of minutes. But John, you've been giving a great deal of thought to the concept of how these things come together and are operationalized in our next body of work. So let me turn to you for some comments in that area.

John Halamka – Harvard Medical School – Chief Information Officer
Well, whenever I think of standards, I always think of content standards, vocabulary standards, transmission standards and, of course, privacy and security, always foundational. Today, we've been guided by meaningful use in 2011. If you look at 2013 and 2015, there are certain themes, certain domains of transactions that are going to be required, so those will continue to guide us. We'll hear from Dixie's group today about some of the – and with Steve – some about the patient engagement and consumer transactions, a whole suite of transactions that we're going to need to start looking at.

I would say our work ahead is going to be taking the 2013 and 2015 necessary transactions, breaking them into domains, and figuring out how we attack those domains. And overlaying that, and this is where I think things do change, not only meaningful use, but now we have healthcare reform, and here we have a set of administrative transactions that have both policy and technology implications, and figuring out how to organize ourselves to deal with this work that's actually outside of meaningful use. I thought they weren't allowed to give you anything outside of meaningful use. What was this healthcare reform thing all about?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Meaningful use of what is the question.

John Halamka – Harvard Medical School – Chief Information Officer
Yes, indeed. And so we'll have to take on that work in some fashion. It may require that we have some joint working groups between policy and standards to get that work done. And I think then the overarching question, as we look at that content vocabulary, transmission, privacy, security, add to that these things outside of meaningful use is, what are the structures? What are the formalisms that we use? And we'll hear from Doug a little bit today on some of his modeling ideas. But I think our next meeting will largely, and through the summer, we'll be working through some of the modeling to make sure we have a framework for laying all this out in a coherent fashion.

I look at what are the successes and failures of previous efforts, the AHIC activities, the HITSP activities, and having a set of isolated use cases that don't connect all the dots doesn't really get us to where we need to be, so we want to make sure there's some sort of overarching framework we can all say, yes. We've identified the 20 different domains that we think we all need to address. And, oh, based on our work to date with meaningful use, we've done 1, 5, 7, and 13, and here are 3 that we still have to work on. And then when we're done with all this in 2015, there's actually a complete, coherent set of all those data elements we need to exchange for various purposes that can be easily extended as new architectures and new requirements arise. The last thing that we want to do is create something so monolithic it's not repurposeable.

An example in my discussion this morning with John and Doug, some of the work that we've all done in the past has used certain architectures that worked great in the past, but we've got new architectures that are emerging. You're starting to see some creative thinking in NHIN direct. In my own locality, eClinicalWorks as a company and I don't mention them as a particular example of a company, I mean, there are many, many fine EHR companies.

But they said, you know, Facebook exists and is used by a lot of people, and it seems to be pretty successful. What if we create Facebook for EHRs? Maybe clinicians, instead of having to buy some product or build something complex, just uses something very, very simple that's like Facebook. Suddenly, hundreds of clinicians just said, sure; that sounds cool. And so I want to make sure too, as we look at all these domains, and come up with these various standards, that we afford the flexibility for supporting those sorts of things we don't even know about yet that could evolve organically, as I'm seeing happen in our marketplace. And I think that adheres to some of the basic implementation group principles that we've articulated in the past.

Today's agenda, I look forward to it. We'll hear reports from all of our committees. We'll have a good discussion about some of the administrative transactions that have been now handed to us, at least in part, and then we'll hear about the DEA and its new e-prescribing rules for controlled substances, which are going to be very exciting. I say that seriously because I believe that physicians will now adopt e-

prescribing much more rapidly when there's a singular workflow, whether it's Lipitor or Valium. It's just one way to do it. It's going to be great. Thanks for all you've done, and look forward to the day.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, John. A perfect tee up and a lot of work, a lot of exciting things and, indeed, I share your enthusiasm for the DEA coming to the table and moving things forward really just helps … safety, quality, value, efficiency, all of the things that this work aspires to support.

Let's move into the first order of business, which is approval of the minutes. Everyone has had a chance to look through those. Please let me know if you have any amendments, corrections, etc. I'd offer the first one. The minutes are spectacular, as always, in terms of their capturing of depth, but on page seven, the word "government" is supposed to be "governance" of standards development. Just a little typo, I'm sure. Any other comments or additions? Then without objection, we'll declare a consensus on those and move to the first presentation today.

I know that Aneesh, the President's chief technology officer, has a conflict at this moment. I hope he may join later, but will be ably led for the first order of business of implementation by Cris Ross, and look forward to those comments. As mentioned earlier, we'll segue into some stage setting for future work, as John Halamka mentioned, by Doug Fridsma after that, so Cris, without further ado.

Cris Ross – MinuteClinic – CIO
Our update is just oral this morning, and it is we had been focusing in the implementation workgroup on a series of work that began with trying to understand from people who had implemented innovation inside healthcare and outside healthcare, what were the real messages that we needed to hear around success. Then we wanted to find some success stories from vendors and their partners. The conclusion of that sort of stream of work is belief that what we really need is something that Aneesh has referred to as implementation toolkits.

How can we make resources available that might be the standards materials, but it might also be resources available from vendors or from interest groups or from examples of successful implementation so that the vision is that if there's a small physician practice that is not connected to a sophisticated provider, how can they find tools to get them started? To find a place where I can just go to get resources in a noncommercial kind of way to begin their effort at implementation.

One of the things that we hope to piggyback on was brought to our attention by John Halamka, which is one of a series of RFPs that's been issued by ONC. This particular one has the project title of Standards and *Interoperability Framework: Interoperability Tools and Standards Repository*, with the keyword there being repository. And we think that the things that we're trying to accomplish with the implementation workgroup are a fairly natural fit with what the RFP is already calling for, which is to provide some structured places for resources to be available to the public to begin implementation. So that RFP has not yet been awarded, and we hope to have some ONC staff work more closely with the implementation workgroup in order to assist that coordination, so that we can see some of those objectives built into the award once the work begins under the RFP.

Liz, what do you want to add to that, please?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Not much. That's great, John. This is Liz Johnson. I think there are two other things that we want to bring to the committee's attention. One is, very recently a $19 million communications grant was awarded. And, as part of that, we're going to begin to collect two-page – and we're saying this because

we were clearly told – two-page success stories that we could begin to, in some way, publish, and we haven't determined via Jodi how we could do that because you have to be, obviously, concerned about the endorsement issues and so on. But we'll begin to work on that.

Then sort of dovetailing with what Cris talked about, remember this is that concept of the cross-reference, easy to get through, library that we think we can make actually happen now with this RFP. So I think our work, we're anxious to hear what is in the future for implementation because I think that is really what many constituents are waiting for. They want to do this. They want to do it right, and they are waiting for our guidance.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, Liz. That turns out to be—and Cris—a terrific segue to the discussion. But before we get to that, let me just open the floor for any comments or input to the framing of the discussion. Cris, you wanted—?

Cris Ross – MinuteClinic – CIO
No, I'm sorry. I also think John brought this to our attention and suggested this is a pretty powerful route, so I want to make sure, if there's something that John wants to add to this, that we hear from him.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Sure.

John Halamka – Harvard Medical School – Chief Information Officer
Doug has provided, and on my blog you'll find this list, of all of the RFPs that fit into his standards and interoperability framework or the ONC standards and interoperability framework vision. And so when you look through that, you'll see that there's spec writing. There are repositories for standards. There are quite a significant number of these RFPs, and so it would seem, and we'll have this follow on discussion after your comments with Doug, to coordinate everything in that interoperability framework that you have laid out with the fine work that these folks are suggesting.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Good. Thanks, John. Indeed, I actually brought that blog as my own internal reference. I think that does help, and I really do recommend that as a resource in terms of defining some of the elements of the forthcoming discussion.

We use the principle for discussion here as always to just tilt your tent card up on this edge. I know, Carol Diamond, you wanted to weigh in first.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Not to be first, but I do want to make a comment. I like what you're sort of describing as what you've found and what the next steps are. I wonder if, you know, just listening to the word implementation is such a big term. It means so much, everything from the implementation maybe of a standards specification, to the actual implementation in the real world in a particular setting, and because healthcare is such a heterogenous environment. You have small doc practices. You have large, integrated delivery systems. It's hard to imagine that you could get all the implementation nuggets in one place.

And so it makes me wonder whether you've considered the distribution of those implementation efforts. I was thinking even since there is a plurality of certifiers now, those certification entities could specialize in certain areas like certain ones might be more geared toward primary care and their collecting sort of those implementation nuggets. All of this, I think, factors into not just the actual implementation of the

standards, but the decision to purchase, and the more support there is for those kinds of things and the more specialized the market can make itself, even the regional extension centers, I think the more likely it is that there'll be something of value for this sort of wide array of people who need to benefit from these resources. So I just raise it as something potentially to consider.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Cris … Liz, you may want to respond because I know these are concepts you've been thinking about a great deal.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I think channel distribution is what I hear, and understanding how you would access those channels, and I think that may be part of the reference and the cataloging, but also having a framework for distribution, so they could understand the way it works. Is that what you're saying, Carol?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. I'm just saying that there are a lot of resources that could be brought to bear, and trying to sort of do it all in one place or centralize all things implementation for the entire nation in one place seems like an impossible task. But that there's a lot of opportunity to distribute that knowledge creation and distribute that function in a way that allows the different entities in the marketplace, whether they're the regional extension centers or the certification entities or what have you, or even entities we haven't thought of yet, to specialize in helping make certain segments of the market more ready for implementation.

Cris Ross – MinuteClinic – CIO
As you know, the implementation workgroup has taken on a relatively expansive view of let's try and identify all the possible things that would get in the way so that we don't look back three years from now and say, "Oh gosh. These were all great ideas, but they just didn't happen." But I think you've set a nice agenda for things we might raise in the next workgroup meeting around how do we segment that and what do we focus on? You know we've had a big focus on help support the little guy, but don't get in the way of the big guy. Those kinds of principles, simple implementation and so on, the implementation workgroup is not going to be, cannot be the key engine for successful implementation. The regional centers, as you say, and other things that you mentioned, certification groups and so on, have to be pretty key to it. But I think those are great comments about what we might raise as next agendas for the implementation workgroup.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Upcoming meeting.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great, let's go to Chris Chute and then Jim Walker, and then we'll go to the Doug Fridsma to segue into the next conversation.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Thank you. I think we all share the vision that you've outlined, at least in principle. But building on what Carol had said, to what degree do you think you can, we can, I'm not sure who should do this, identify a federated model of required infrastructure that can enable these kinds of implementation visions that you have. For example, it seems obvious, and it's been discussed in the vocabulary working group, that having a national repository of value sets is going to be real handy to anybody, whether they be independent physicians working through a mediator, or whether they be large organizations or vendors, and is, I think, an example of the kind of critical component infrastructure. And I submit there are

probably a flotilla of components that need to be in a federated enterprise available to enable the kind of distributed engagement that I think you're characterizing.

So the question is who and how should we go about identifying which of these components are critical paths, which of these might be best managed in a quasi centralized fashion, and which of these can exist in a true, distributed, let a thousand flowers bloom effectively, kind of model because, I think, for some elements, user interface for example, it's entirely plausible that there's no reason to have that centralized or locked down. But there are other components that are core to interoperability that clearly must be. And, furthermore, we don't want everybody reinventing, so segmenting the task in that fashion, I think, would be helpful.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think your comments, Chris, again are a perfect segue to some of Doug's. That's one to think of the broader concept of an interoperability framework and the different elements. What are tactical supports and what would a strategic and implies a sort of directionality. In reference to a previous set of comments, is flexible enough to accommodate future development, yet doesn't disenfranchise or phrased another way, what retains backward compatibility, and so all of those elements are very practical and, in a sense, also very strategic and need to come together. Again, I think, form the basis of good introductions for some of Doug's comments.

John, I don't know if there's anything at this juncture you want to add. I know you've been thinking a great deal about this. I think, Jim Walker, you had a card up.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Great work. This is Jim Walker. Having helped build some of these toolkits or other sorts of toolkits, I just really urge us to do as much as we can to use really good, user centered design, and try to set aside some resources for measuring which parts of these things work for which audiences. That rarely happens with toolkits, and the toolkit developers are characteristically dismayed at the usage patterns of their kits.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great comments. Lots of heads nodding in the room on those comments. Dixie Baker?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. I just wanted to bring to your attention also on behalf of CITA that NIST is in the process of issuing a couple of RFPs for tools that would use the secure content automation protocol, SCAP, to validate compliance with HIPAA, and these are tools that they'll be developing through those solicitations. I would encourage you to look at that as well.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you. Wes Rishel?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks. See, I didn't go first. Section 1104 of the HCERA, which might be called the HIPAA … portion of the … has a number of initiatives that bear on what we do under meaningful use. They're directed through NCVHS. But certainly the work around finding operating principles is similar to some of the implementation work we have to do. I recognize that it's possible to over-coordinate, but is there any coordination plan between these two initiatives?

David Blumenthal – Department of HHS – National Coordinator for Health IT

I guess there should be.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Sorry.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Do you want to say more about—?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
When we look at these series of initiatives that have come out, a portion of them are about creating profiles for how standards fit together in making that, making and creating a repository of the specification information so that you can create a profile without going through the terrible, awful things that HITSP had to do. Without trying to read too strongly into the language of Congress, the bill alludes to the work of the CAQH CORE group, and that is a similar effort in terms of its capabilities. It also, however, creates penalties on health plans for noncompliance that are pretty substantial.

David Blumenthal – Department of HHS – National Coordinator for Health IT
So these are the administrative simplification provisions?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
That's right. Yes.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Okay. Yes. And we are required to coordinate with them or at least to be informed. I missed your reference … content, so NCVHS has traditionally led in providing advice on matters related to the administrative simplification, administrative standards part of HIPAA. And it has also provided a lot of … security side of HIPAA. And I think that the plans actually strongly supported the idea of moving HIPAA to its logical conclusion, which is the development a single set of standards for exchanging, and the implementation of standards for exchanging billing information.

There is actually in the material that we're going to be talking about a requirement that the policy committee and the standards committee go beyond administrative simplification to look at enrollment and the simplification of enrollment, both within and outside the healthcare area. But we will, I think, as NCVHS gears up and starts working on the administrative simplification work, I hope, be bringing in our groups, the actual— I think the law references the policy committee, as I recall, but not the standards committee. By law, the policy committee has to be consulted. The standards committee does not. But there's no reason why we can't get your views to inform the policy committee—

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David Blumenthal – Department of HHS – National Coordinator for Health IT
No, this is a different section.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Just one question. How broadly is the enrollment? Is that enrollment in the health plan or enrollment in any program, enrollment in Medi-Cal or Medicaid, for example? How broadly is—?

David Blumenthal – Department of HHS – National Coordinator for Health IT

It's very broad in Section 1561, but in the administrative simplification section, which is a different section—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Sure.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Sorry?

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David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes. The reference is solely to finalize the implementation of the HIPAA vision of a uniform billing process.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Wes, for that. I think there'll be some parking lot issues, and some of that will certainly, again, converge with, I think, some of the conversations that Doug will be bringing forth. Let's take the last comment on this portion from Cita Furlani and then move to Doug, in fact for that discussion.

Cita Furlani – NIST – Director
Thank you, John. I just wanted to thank Dixie, but also wanted to mention, pick up on the user centered usability issue because that's one of our primary concerns, and we are insuring that that research that we've long been engaged in will be applicable to these toolsets.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific. With that, Doug, the floor is yours, and look forward to hearing some of your thinking about the directionality of tying these components together.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Thanks, John. I don't have much in the way of prepared slides since we talked about this about 45 minutes ago.

Jonathan Perlin – Hospital Corporation of America – CMO & President
So it's very fresh in your mind.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
But I do have a slide deck—I just happen to have one that is now being projected. This is actually a presentation that you all saw at the last meeting that we had together. I think what I wanted to do was just pull out one or two of the slides here and use that sort of as a backdrop to frame some of our discussion, and also to answer some of the questions around the RPF out there about tools and repository and sort of what we were thinking with regard to that. And I think we are thinking about things in very similar ways, and to get some clarity and to help answer some questions about that as well.

I am just going to flip right to this slide, which really, if you remember from last month, described this coordination framework or this standards and interoperability framework that corresponds to many of the RFPs that have been issued and that I think has provided, is put up there as a straw man to see if we can't provide a mechanism for coordinating the work, not only around meaningful use, but also on some of these new things that are coming on to our plate around administrative transactions and healthcare

reform. I think, first, to address the issue around tools and repository RFP, so if you take a look at this particular diagram, at the very bottom is tools and services, and this is all about kind of developing the kinds of resources that we need that will support this process and make it more self serve than something that we have to handcraft each time. So when the RFP was written, it was written to be essentially a framework in which we could identify and prioritize tools that would support the process, a way of selecting the projects to work on, and then creating mechanisms to fund them.

The actual RFP gives examples of things that could be funded, but doesn't specifically say that they need to be built as part of this. In fact, the goal is to create a mechanism, as things came up, that would allow us to fund those priorities and provide that kind of support. We also have flexibility in something called the detailed technical letter that allows us, within the scope of the RFP, to create a direction or a focus and essentially redirect some of the resources in a way that would support the mission, if the mission that we have changes. That was sort of the genesis or the ideas behind that RFP. The goal, again, was to provide a mechanism so that work that's being done on developing sort of the core concepts, the building blocks, if you will, the recipes that we used to sort of develop the software so that people could begin having a self-serve or the ability to sort of access those things directly. I look forward to actually learning more from the implementation group and seeing how we can support some of those activities.

Jonathan Perlin – Hospital Corporation of America – CMO & President
So if we take, as a use case, we now have this framework and the RFPs, and we now have healthcare reform and Section 3021 that says actually there's a set of administrative transactions to include such things as the enrollment transaction. And one that I think is particularly interesting is electronic matching against federal and state data, vital records, employment history, enrollment systems, tax records, and other data determined by the Secretary as appropriate evidence of eligibility. I take that as marching orders to develop a national healthcare identifier. What do you think? Just kidding. Just kidding. Reject that from the record.

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…kidding.

Jonathan Perlin – Hospital Corporation of America – CMO & President
But, no, I mean, what I mean by looking at number one is this is a very heady body of work and, now, I mean, Cris, to your point. There are policy implications. There are standards implications. There are functional implications. And so this is something, to me, that goes beyond the scope of any taskforce or workgroup that we might just create on our own in this federal advisory committee.

What I would suggest is, Doug and the wise folks at ONC, given that we now have a set of marching orders, and you have a set of frameworks, how might we use this as a test case for exercising your framework?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Yes. I think we want to, whenever we're sort of setting up a framework or trying to do this work, the more we can ground it in the actual work that we're trying to get done, the less abstract we are about sort of how we want to do this and actually dive down into the work and see what problems need to be addressed. I think we'll come out at the end with a better product, both in terms of the standards that get developed and the framework that we use to develop them than if we do this in the abstract and then see if perhaps it works. So I agree with you. I think using some of these use cases to drive through as examples and see where the problems are, where the challenges are, how we can make this better is, I think, a good approach.

John Halamka – Harvard Medical School – Chief Information Officer
Because it may be that we have to organize ourselves differently and in novel ways. Like for this particular case, it sounds to me like a joint taskforce for tiger team between policy and standards working on some of these administrative issues. It isn't just as simple as saying there's an X12 transaction for that. We're done.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I want to just endorse or associate with your comment about not being done in the abstract. I think the other thing, and whatever the appropriate structure is, John, for this to occur is there has to be – I mean, when one thinks about interoperability framework in the abstract, and I know a number of us have been looking at other countries and how they consider. There is an architectural coherence that's implied, which in turn implies a set of principles. I think that group might work with ONC to define some of those principles so that in fact the work that's conducted is not only grounded in concrete and necessary activities, but also comes together to create a coherent or at least the basis for a coherent whole with the implication of directionality and, as mentioned earlier, the backward compatibility.

I've seen a number of cards go up for discussion, and really look forward to this part of the discussion. Before we go to that, Doug, any other comments that you might want to offer in terms of framing this next round of comments?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
No, I think what you bring up is an important point, which is having direction around principles for architecture, so what are the things that we would like to see in a good framework, model, or whatever you might want to call it, things like flexibility, extensibility. There are some basic things that we need to apply that tell us whether A is better than B or how to make some choices. I think that kind of guidance from a group like this is very helpful.

I think the other thing that's important, and you sort of allude to it, is that in addition to sort of having the model or the architecture that helps coordinate things, there also needs to be coordination and management around the people and the decisions that need to get made and things like that, and there are different models for doing that. And I think that's another aspect of the discussion that may be helpful is to think about how we can manage and coordinate these processes such that it can be open and transparent, and we are inclusive. But, at the same time, being able to meet our objectives and our goals in sort of moving the ball forward. I think that's another area that is going to be important to get input from this group.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, Doug. That's terrific. Let's go around and take … Cris, appreciate your perspective, Nancy, and then we'll go to Carol Diamond and then Chris Chute.

Cris Ross – MinuteClinic – CIO
Just briefly, this is Cris Ross. Doug's presentation is perfect, and I think the implementation workgroup, again, is an advisory committee, not a workgroup. We don't have staff. We don't have resources. Attempted to create some dialog with the community, and we found that there was a hunger to say, gosh, we really need these resources to get things done and a desire to participate. We've done some good stuff, and we'd like to share.

I think I want to make clear that I think the implementation workgroup, just speaking for myself, and I assume the other members of the committee would probably take the same viewpoint. We want to say go as fast as you can, and we don't want to get in the way. I think, if there's a flavor that came out of the

implementation workgroup is all the things that we've sort of plowed before that one size doesn't fit all; that we do need to get to the issues that Carol talked about, about partitioning different solutions for different people and all the rest. And I'm hoping that we can better combine the great work you're doing with comments from the public and work of the workgroup to sort of fine-tune what you're doing, but this is what we're trying to build on.

I think we had a meeting on the 30th of March where it became obvious that there was no way that an advisory committee doing do-it-yourself kinds of things could meet any of the desire and needs of the community, and we wanted to piggyback on your work. So just as context, I wanted to be clear about that. I don't think there's any competitive or at odds kind of work here at all. I think it's all the same work.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We're really hearing very clear call for … infrastructure of support, resources, and that's fair, understandable. Nancy Orvis?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Yes. Doug, I'm glad you brought this interoperability framework up, and I've used what you've introduced last month to generate a lot of dialog among different folks within our organization and probably with some of our providers that we exchange with. I think there are some real critical pieces that we need to mature in terms of, one is, John mentioned like some categories of standards. I think a lot of folks, whether they're CIOs or whatever say, "Okay, my IP people are taking care of standards. Yes, we do them. We do them."

But what John mentioned is we're talking a lot about content standards, vocabulary, transmission, and security and privacy. And there's a wide variety of maturity in all of those, and I think what you're trying to convey, and we need to continue to convey, is that NHIN will only go as fast as the maturity across all of those. You have a thousand flowers blooming, but you can't say just because you've figured out this piece, content, we still have the issue of addressing specifications, and you're not going to be able to send it until you get the addressing stuff done right.

I'm trying to find some ways that we can tell folks that this analogy may be similar to when we first started electronic banking 20 years ago. It used to be you got a card just for your bank. You couldn't use it at anybody else's bank. Then you were able to go in your own city. But you could never deposit in anything other than your own bank. There are some issues, and it took five, ten years to go across the nation, and now around the world, to do ATM cards around here. That was a 15-year maturation.

We need to figure out some ways to help folks understand that there are little pieces. We may want to come up with a defined set of categories of standards. I've used one internally with the Veterans Affairs and federal health for a number of years. We have data representation standards. We have modeling standards. We have communication, technical, security, whatever. And, to me, that helps a lot of folks, including implementers, developers, and engineers understand what level you're trying to speak to because they certainly realize that there's a panoply of standards. And if you don't specify which group you're talking about, they can get very confused.

That's one thing I'm thinking that this work on the interoperability framework, we would certainly welcome that idea to help you mature the discussion in this area. It's a complex area that the nation needs to understand better that we're all taking different steps. And I think another example is if you go to a Web site and you only get the answer 60% of the time, you're not going to use that Web site until somebody tells you that 99% of the time you go there, you get what you think you're going to get. And you need to say, we're going to build demonstrations and prototypes, but until all that fully trusts, that I fully trust that

that's a site that I'm expecting to get, that's the information I expect to get, that we're going to be working on building this interoperability and the maturity. Perhaps that's just my second comment that we might be looking at an interoperability maturity piece to go along with this framework so that we can fully understand that. Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Before we go on, John or Doug wants to respond to that because I think your comments are really very … in terms of thinking about what an interoperability framework implies in terms of architecture. Yes, there's a certain sort of bottlenecks or limits in terms of those areas if one sort of categorizes the standards in different areas where further work needs to be done. That in and of itself is helpful, but the reciprocal of that is that it also helps to identify where there is a maturity and reference sets that actually can be used to help model. I don't know if John or Doug wants to expand.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
If I could just respond real quickly, I also was thinking about if any of us still remember when there were bulletin boards in CompuServe, and those little black and white screens on the Internet. You had to really want to be on there to communicate versus a bulletin board, and I think that's another piece that we need to say that those are the early adopters that went on and said, "Yes. Go over and learn these user groups, and we'll figure out how you can get on the bulletin board." Some of this, and these prototypes, and these demonstrations, we're doing some of the equivalent. Well, did it post the way it expected it to? Was there a difference in the spec, so it looks different than we thought? And I think we can make this very positive.

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Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Yes, but we'd certainly like to get some more. I think that's part of the interoperability framework too that we manage expectations in what we're going to get.

John Halamka – Harvard Medical School – Chief Information Officer
A quick lesson learned from Canada. As Canada … harmonization, one of the things they did was not use cases, but more domain cases. And what they said was, in the domain of medications, we know medications are quite important to meaningful use. There's e-prescribing. There's medication reconciliation. There's supply chain. There are many components to that entire suite of the medication management domain. And it was, let's get all of those pieces and parts of the suite done because then you get to the 99% of the ecosystem being able to do what they need to do. The interesting example you gave from the ATMs, I mean, sure there was the technology. Yes, we did a … standard that enabled us to send data from place-to-place, but so much of that 15 years was developing policy, trust, and workflow.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Yes, and it's not a technology issue. It is absolutely a policy and an organization to organizational policy and how you expect, how customers and vendors are going to understand what they're doing, and can they trust what they're getting?

John Halamka – Harvard Medical School – Chief Information Officer
Right, so I just think we absolutely need a framework, which enables us to state what are those technologies we have in place, and we think about them as domains. That's going to be very, very helpful because we'll see what's missing, to your point, and then make sure, as part of the framework,

and you've outlined this, reference implementations and testing, real world instantiations so there can start being the trust, the workflow, and the policies around it.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's stay on this topic for a moment. I know Dr. Blumenthal might want to—

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes. I appreciate these comments. They're very instructive. The thing that we, and the responsibility that the Office of the National Coordinator has, which is new, is that we've been instructed by the Congress to develop a nationwide, interoperable, private and secure, electronic health information system. We're not, in some sense, in the passive mode of waiting for all the pertinent parties to come together spontaneously. We have a mandate to try to lead this. And, at a minimum, it seems our responsibility is to develop the standards and implementation specifications and certification criteria, which, if the political will exists, would support interoperability, and to do so as fast as we possibly can.

That points back to what John Perlin said, which is the need, and John Halamka just reiterated, the need for the policy committee and this committee to make sure that the National Coordinator knows exactly where we have adequate standards and specifications, and where we don't. And, in the areas where we don't, points us in the direction that will enable us to develop them, and Doug stands ready to help. But we can't stand back and kind of say we're just going to wait and see what happens. Because, when it's ready, it will happen. That may have been okay in some cases historically, but it's not okay any more.

We really do need your help in saying the world has not spontaneously produced something that we need in this area or in this area, and it ought to take this shape, and this is what it ought to be able to do, and go make it happen. We can't make everyone use it, use those standard specifications, but we ought to have them available so that when people come to the conclusion that it's time because the economic incentives are lined up or because they just made the psychological shift to saying I can't live anymore with the fractured health system that makes it impossible for me to know what's happening to my patients across town. That it will happen as rapidly as possible.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, David. Appreciate the reiteration of the call to action, and I think it's a good theme to frame our next set of comments. Let's go around the table: Carol Diamond, Chris Chute, and Wes Rishel.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. First, just I want to say that I think ONC has the opportunity to do something much more impactful, and CMS, something much more impactful than specifying standards because we have a lot of standards that are highly specified that really don't get used. The opportunity you have with CMS is to really make the exchange of information and the sharing of information have value. And, by doing that, once you have that framework, you can identify where there may be standards needed and where development is needed. But I would argue the much more significant opportunity here is to make sure that meaningful use really requires the use of those standards. In other words, when you want to achieve meaningful use goals, you have to achieve some of the interoperability requirements, and these standards are going to be identified and specified, but that's really not the thrust of what I want to say.

I want to wave a little bit of a flag here, both in terms of the slide – I was not at the last meeting, so I looked at these slides kind of fresh again. And the flag is you said we're looking for some guidance on the architectural model, and I've heard other people talk about the importance of policy. And I think, as a function of just, we've been doing a lot of things in different groups, somewhat disconnected from each other. The coordination framework here must include a policy framework, and it's really not on this slide.

And my worry is that although we have the NHIN workgroup sort of talking about a trust framework, we have the privacy and security workgroup working on a policy framework. We have a subcommittee in the NHIN Direct doing some privacy and security stuff. We have our own privacy and security workgroup. If the NHIN is truly policy standards and services, then policies need to be factored in here in a wholistic way and in a way that can guide things. And I say that because input on architecture is essentially input on policy.

We've long said in our work that architecture is policy. It makes determinations about where information is, how it's shared, who has access to it. And I really think that we've reached a level of maturity, I think, in all of these groups and in all these discussions that it is really time to coordinate frameworks and to really make sure that, as the NHIN Direct work proceeds, it has the answers that it needs. And, as the policy work proceeds, it has the answers that it needs in terms of technology. It is a mistake to uncouple these completely because one can't catch up with the other, and unhinged, I think, sometimes you end up with technology making policy because you have to. You have to make some decisions.

So if I were in the NHIN Direct workgroup, I'd be raising my hand now saying, we need guidance on some policy issues because we're getting to the point where we're starting to sort of hit up against some issues that need that kind of input. And if I were on the policy committee, I'd be saying, is this possible. Can we do this technologically? Where are we in terms of architectural determinations on some of these issues?

So I just want to put out there that I think it really behooved the work. I'm on the NHIN workgroup, but I feel a little bit disconnected from this and from the other policy framework that's going on. And I wonder if we could consider how to create a wholistic view here, including in the way we talk about the NHIN coordination framework that can start to move things in a way where policy and technology are informing each other as opposed to kind of happening in different areas.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Carol, I think those are very important and very good comments. I think you're absolutely right. I think it is embedded within this framework some notion, and as we define the NHIN as being services, standards, and policies, part of implementation specification is policy. I think one of the things that we need to think about, and I just sort of throw this back as a question.

As we think about creating technology that is more building block and more modular in its approach so that we can take different components, assemble them to solve a particular problem, we may want to think about policy in similar ways. If we have a monolithic policy, it becomes hard to really then apply that with the technology that is a set of building blocks. So we need to make sure that, as you say, technology and policy need to work together synergistically.

We need to also think about policy in a way that may be building blocks or components or other things, so that we have the same kind of flexibility that we have from the technology side because, I think, making sure that there's no impedance mismatch, if you will, between policy and technology will enable the kind of vision that you have to come to fruition, and so we may need to think, from a policy perspective, how can we create the tools, the building blocks, the other things that we need to be able to support this as well.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
In fact, it's necessary for policy as well. You can't talk about policy in the abstract. You really have to understand once you get beyond the sort of principle level, which I would argue that should be consistent. It will be consistent for technology as well. There are certain high level principles that you're adhering to,

and high-level principles this committed has created. But once you get past that principle level, both policy and technology have to be thought of in a way that doesn't have an impedance mismatch, in a way that meets the needs. And that's only, you only get there by defining the practices and the policies that are necessary to fulfill those principles, and they will be specific to how and in what context you're talking about information sharing. I'm right there with you, all the more reason.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great discussion, and I'm pleased about the direction this has taken because, Carol, I'm sharing a little schematic I'd written down when Dr. Blumenthal had identified that the mandate clearly is the system that's nationwide, interoperable, private, and secure. I wrote down technology in one hand, policy on the other, and underlying both, what exists, what's absent, and then what exists, what's available in terms of tools, resources, reference implementations, and what needs yet to be developed. And that sort of modularity that has been discussed also finds its way into what conceptually, and certainly in other countries are the elements of an interoperability framework. This is a very healthy direction in the discussion.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Can I make one final …? I just want to say that policy doesn't have to be thought of either as some big pie in the sky set of issues. There are policy determinations very often that get made in a specific standard because of where it keeps metadata or how it looks at the underlying information, and having a policy framework can make the standard selection process and the specification process much simpler because you take some options off the table if the policies clear.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well said. I believe we have Chris Chute, Wes Rishel, and then Dixie Baker, and then we'll move back in, but terrific framing discussion. Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Doug, you know I'm a great fan of overarching frameworks and cohesion and integration. I do want to raise a question where there's an implicit tension, and that is the scope and engagement of this process. I'll choose to wear my hat for these comments as chair of ISO TC215 on health informatics, who are seeking this question of coherence and alignment where what we develop in the international community ideally should be coherent, that is, adhere to a rational framework. And, oh by the way, align with community needs and requirements in particular nations.

The tension is we can't solve world hunger. It's hard enough to get agreement within country. To what extent is it even feasible to engage this process in a larger scope? And I don't presume that you should answer that question, but I did want to raise the issue of openness in that the RFAs that form the heart of much of this discussion are still behind a password protected firewall. And to the degree to which technical content exists in them, that could be liberated, I'm not saying the whole RFA has to be liberated, but people are asking. So what does this really mean? Is there a secret agenda?

I know there isn't because I know you, and I know ONC, but it gets at this perception and question of how do we engage the interested community both within the country, and I might add, internationally. As you know, there has been formed this joint initiative council, which is a bunch of SDOs and ISO trying to align purpose and content so that we recognize from the get go we're in a global market. We recognize that the ATM card eventually will want to work internationally. And we recognize that it doesn't make sense to reinvent these in a parochial, domestic fashion, particularly if that engenders potential incompatibility and inconsistency in a world market.

I know a lot of vendors are deeply concerned about having boutique niche standards within each country or within each domain. It's something to be avoided. So I'm not suggesting that you embrace the global problem. I know it's a big enough task to do it back home. But I am suggesting that, to the extent practical, we keep as much of this information as open and public as possible, ideally all of it. And, furthermore, we entertain in the early stages, well, what is sensible to seek international concurrence, maybe on the overarching principles, if not the detail.

Policy becomes an interesting question, and I agree, Carol, that policy and standards are deeply intertwined. Trying to get international consensus on policies, I've heard, a bit of a challenge. But, nevertheless, having consensus on the overarching principles and some of the technical specifications to the extent that we can get, if you will, simple policies agreed upon, non-threatening policies agreed upon, I think we'd go a long way.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I feel like I'm climbing back up on an old soapbox here. We have adopted some implementation principles or guiding principles that involve looking at what has been done in making incremental progress as opposed to solving the whole issue at once. And we did that because we saw more progress through evolution of the standards and the understanding of the business needs together. And I think that has been a major step forward for us.

I think about all of the technology issues associated with the ATM, all of the policy issues associated with the ATM, and we haven't talked about the single biggest issue that may take 15 years, which is with the banks first had to decide it was not in their interest to control the data, and then second, they had to decide it was worth the investments to share the data. Two separate decisions, both important to get there. We will, throughout all of our lives, and I go for even you young people, we will continue to struggle between getting a coherent picture and getting something done, knowing that the rest of the picture is incoherent. And I just don't want to see us swing back towards we've got to get everything in place and nailed down before we move forward.

We have an opportunity right now because the stimulus bill created an artifical economic incentive for interoperability. And if we have achieved that interoperability at the end of that artificial incentive, we have a good chance to coast. Once people have made that investment, gotten over the issue of do I really want to share this data, gotten some of the mechanics out of the way, it's easier to keep going. So we should keep in mind that we're working in an environment where no standard is ever complete. I think it was the words complete standards that keyed this whole diatribe here.

No standard is every complete. They're always evolving. We're aware, because ONC has worked hard with this committee to try to deal with the issue, that the feedback loop necessary to make standards, first of all, usable and, second of all, continue to evolve as fast as the industry does is incompatible with the regulatory environment. And so I just urge us to continue to look for incremental areas to make progress and the ability for people who want to take use of this artificial incentive to do so in the timeframe that they can. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks. Dixie, I think you're up.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I just wanted to respond to Carol's comment, not that I disagree. I totally agree that policy and technology need to go hand-in-hand and these efforts that seem to be separate need to be brought together. But I don't want people to think that there aren't efforts that are working together right now. I serve on the privacy and security policy committee, and that policy committee right now is addressing NHIN Direct and security and privacy policies that go with NHIN Direct, so these workgroups may seem to be autonomous and compartmented, but they really aren't.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Kevin Hutchinson ….

John Halamka – Harvard Medical School – Chief Information Officer
The last word on this.

Kevin Hutchinson – Prematics, Inc. – CEO
Mine is a general statement because I've been listening to the very thoughtful comments around policy and technology and the frameworks. And in remembering the conversations that we had at the last meeting, one of the things I love about doing startup companies, and I kind of view this organization as a startup organization, is that we morph. As the environment changes, it's very, very important to continue to do a gut check to see if we are structured and focused on the right things, as the environments change. And it occurs to me during this conversation that a lot has changed since we established this group early last year, and I wonder if we shouldn't step back.

I hope this isn't heresy, what I'm about to say, but that we step back a bit and look at how we are structured within our workgroups, and are we structured for the environment changes that have happened? For example, is the clinical quality workgroup and the clinical operations workgroup, is this really things that are starting to come closer together? I look at the first box on the slide talking about use case development and had a little bit of experience with use case development back in the AHIC days, and we were way too down in the weeds specific to how does a lab order get to a certain – and we have to come up to a broader use case about how healthcare actually operates. And shouldn't we be coordinating and organizing ourselves around those kinds of use cases with respect to standards development?

I just bring that up just kind of think in the back of our heads about are we – reassess whether we are structured in the right way to support going forward.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I don't think that heresy at all. In fact, I think that's really one of the fundamental components of this discussion and to go forward is because I think this last round of discussions has really brought up, and Wes' comments that a compelling business context that will drive. How do we capitalize on current incentives? But … that create the durable traction or pull for activities? The interchange Carol and Dixie is that, and Carol … that both policy and standards and technology standards be developed. And then, there is coordination, but I think it still would have to identify that it's imperfect. That needs work as well.

Then I would offer my own sort of observation on the business context is that it's great to develop toolkits, but I'm identifying with Wes' point that there has to be a business rationale to reach into the toolbox and pull them out. We have some very real activity that David has teed up for us in terms of what else is required in terms of not only meeting and supporting the meaningful use activities, but the health reform activity. With that, let me turn to John Halamka because I think you want to tie it back to a very concrete use case, and we'll go from there.

John Halamka – Harvard Medical School – Chief Information Officer
So, Kevin, you're my straight man here. This is great. Which is, I think we are organized appropriately for certain tasks, so the vocabulary taskforce is well organized to achieve that particular end, but Section 1561, which I've referred to multiple times here in healthcare reform, which describes 180 days. The clock is already ticking. We have 149 left. Yes, 149 left, so that the HIT Policy and Standards Committee shall develop interoperable and secure standards for protocols to facilitate enrollment of individuals in many different ways, so there's the patient identity matching.

There's the providing of electronic documentation and digitization for verification of eligibility. There's a reuse of eligibility. There's patient engagement for being involved in the eligibility process. There are rules: cell phones, e-mail communication. You read this thing, and it is enormous. In fact, everything Carol, Dixie, all of us have said, I mean there are policy statements. There are technology statements. There's vocabulary. There's transmission. There's content and security all wrapped into these three pages.

How are we going to get this done in the next 149 days? And so I would hope, after today's discussion, that we all have this sense that Doug has now given us a framework. We have a set of marching orders here, and we have to look at the way that we're going to get this thing done, which may require a novel organization of all working together, and that we give Doug the go ahead to create a straw man plan. That was, of course, ONC broadly of how we might attack this to get there fairly rapidly.

Jonathan Perlin – Hospital Corporation of America – CMO & President
In fact, John and I were thinking that we'd really like to formalize and memorialize that as an endorsement from this group to the Office of the National Coordination and to Doug to bring back some insights or recommendations in terms of interoperability framework and structure to support. Let's take – I'm sorry, David. Go ahead.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I want to add a little bit of context to this section. It sounds, if you just point to it in isolation, it sounds like a somewhat crazy and overly, hopelessly ambitious mandate. So why would anyone task us with this? And the answer is that, as part of the health reform process, Congress and Administration are trying to increase the number of people who have insurance, and they want to make it easy for people to get insurance. They want to make it easy if you're Medicaid eligible to enroll in Medicaid, if you're eligible for CHIP to enroll in CHIP. And if you are eligible for a federal subsidy starting in 2014 when the health insurance exchanges are available, if you're eligible for a federal subsidy to buy private health insurance through the exchange that you can learn that eligibility quickly.

And they want to make it possible for people to do this online, or to do it from the food stamp program if you're going to get food stamps or if you're enrolling in welfare, or if you're going to get your motor vehicle license renewed or wherever, school, school lunch programs, the WIC program, whatever. The point is to make it as easy to buy health insurance as it is to buy a book on Amazon. That is a noble aspiration and one that has actually has been part of the President Obama's healthcare vision from the time he announced his own health plan in May 2007.

However, it does mean that somehow the various systems that support these different social services has to be interoperable in some way, and it's that interoperability that is sought through this Section 1561, and Congress turned to the policy committee and the standards committee to try to give it guidance on this task. Now they set a very, very demanding deadline, 180 days, to do something, which has been the kind of holy grail of social service and health services for what I understand is many years. These programs

talk about technology and policy. These programs were not set up with this vision in mind, so there are huge problems that I don't have the faintest understanding of as yet.

We are beginning a dialog within the department of Health and Human Services, and hopefully shortly across other departments: the U.S. Department of Agriculture, the Housing and Urban Development, IRS, Treasury. All these organizations have regular electronic contact with people who are uninsured and are potentially eligible for substantial federal subsidies or expanded federal programs starting in 2014. Think of us, therefore, in the same way that we are playing the role of facilitating better care through standards and interoperability. We have the opportunity to facilitate better coverage through standards and interoperability. That's what we're about.

Now doing it is, as we've learned today, hard for healthcare. It will also be equally hard for non-healthcare interoperability, and I'm not sure we have around this table all the perspectives that we need. That's one of the things we want to do is, as we consult with our sister agencies, we have within the Department of Health and Human Services, the administration on children and families, the administration on aging. We work with the USDA, Department of Agriculture on their telehealth and broadband programs. So we have to begin to get the expertise around the table, and we will probably be coming back working with John and John about working groups that combine the expertise here with the expertise that we will drawn in from outside.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, David. Let's take a couple last comments on this topic, John Derr and then Janet Corrigan.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
Yes. I'm John Derr. As we look at reorganizing and looking at this, I don't want to add more work to what we're doing, but we look at hospitals and eligible physicians and professionals, but we don't look at long-term, post-acute care. And, to get complete interoperability through the whole spectrum of care, we have to start looking. And I would hoped we would include into our looking at our organization of what we do to look at nursing homes, L tax, homecare, hospice, inpatient therapy, medication management throughout the spectrum of long-term care, and add to the group.

And I can't verify this yet because I was on a clinical committee. Janet and I have talked about because I said, "Can we assume in the quality measurements that long-term, post-acute care is part of the whole thing? Let's look at those." And she's very nicely added long-term care to the different quality measures in 2013.

We, as a profession, are looking at it, but I did find out the other day that there's a possibility that CMS is looking at developing their own transition of care document that they're using the CARE or the MDS3 or the OASIS Charlie, and that makes double work for us. Then later today, I'll comment that the DEA has not looked at long-term, post-acute care, but looking at just ambulatory care. So I'd encourage us, as a group, to look at the whole spectrum of care and not just eligible physicians and eligible hospitals, and sometimes when I talk to CMS, they say, "Well, you're not in the legislation. Therefore, we can't consider you." Well, unless you consider this, where 40% to 60% of the people go to homecare or to hospice, we'll never get interoperability and quality measurements across the spectrum. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I appreciate your reminder and I think, when I contemplate what this group has been instructed to do, and I contemplate the components of meaningful use, when you consider those transactions have to allow for interoperability, let me just state that from my own perspective, I don't … where it doesn't apply. In fact, I think you remind us that we need to, as really the thrust of the earlier discussion, that the implementation

guidance, the framework that ultimately developed implied needs to contemplate the sharing of information across the broadest variety of environments and situations. Importantly, it specifically indicates the patient and so I think we need to contemplate that broadly. Thank you, John, for that reminder. Janet?

Janet Corrigan – National Quality Forum – President & CEO
Just a quick question … comment first. I think this is a really important congressional mandate, and we should try to figure out how to deliver whatever we can to make this work. Realistically though, I don't know what your process is, David. You have to go through some kind of public comments, and do you have to go through a clearance process? Are we really looking at three months to do this work rather than five or six months? What are we—?

David Blumenthal – Department of HHS – National Coordinator for Health IT
One hundred forty-eight and a half days. It's a great question, and I can't say that we have it all figured out yet. We're just trying to scope the problem, frankly, or the challenge. The Department of Health and Human Services has thousands of tasks to accomplish as part of healthcare reform. Hundreds of regulations to write, and many of them were due even before the legislation was signed. And some are due May 1st, and others are due June 1st and July 1st, so to be absolutely frank, anything that isn't due tomorrow hasn't gotten as much attention, but we're sort of putting, sort of shooting, you know, sending a shot across your bow to say this is coming. We're going to try to give you more instructions soon, but it will get to it, but it hasn't been the first thing that took the department's attention.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks. Jodi, were you looking to comment?

Jodi Daniel – ONC – Director Office of Policy & Research
Yes. I think we probably have a little bit of flexibility on what the 180 days applies to and what we need to have within 180 days. It talks about having the standards in consultation with the Secretary and the policy and standards committee within 180 days, and so I think there may be some things that can happen after the 180 days from our standpoint, but we'll have to obviously figure that out from a process perspective. But it's a good question.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I know a number of people have told me that they have conference calls related to a number of overlapping activities at 11:30, and so I want to draw this session to a close, and I'm sure this is a topic we're going to be coming back to. I did hear from John Halamka, and I think this is very important that we memorialize this discussion and, in fact, that with your agreement, with your consensus, if it's the sense of this group that we endorse to Dr. Blumenthal, Doug Fridsma, and the Office of the National Coordinator, to bring back further thinking, both about the activities and spectrum of interoperability framework and recommendations on cross-links necessary for the appropriate structure to support and that rather than try to reiterate all of the very important nuances that there discussed just with reference to the content of this discussion, the recommendations that really arose in terms of the pragmatism and representation, and linkages policy and standards as well.

Agreement with that charge to the National Coordinator and to Doug? Terrific. We'll declare a consensus around that. Doug, thank you very much for really a terrific discussion and thanks to all the members of the committee.

I know that there is much to be discussed. Obviously this is something that both at our next meeting and in the work between meetings, we will be contemplating, so don't fret too much. We'll have opportunity for a lot more discussion. Doug, we look forward to your comments at the next meeting on this.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's move then to privacy and security. Dixie Baker and Steve Findlay, appreciate your leadership and really welcome your update from the workgroup.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay. Welcome back, Steve. Up to this point, we've really focused primarily on security standards, and to some degree privacy standards. But for the most part, the stage one meaningful use requirements are really primarily pretty lightweight in the consumer engagement area. And they get stronger in stages two and three. Today, in addition to updating you on what we're doing in the area of standardization, privacy and security, we also wanted to explore with you some of the needs for standards that are coming down the pike in stage two and stage three and, indeed, it sounds like Section 1561 has some consumer engagement aspects as well.

First, do I have the giver? No. As I mentioned earlier, I've been serving on the privacy and security policy workgroup as well, and that workgroup has been focused heavily on consent and permissions, whether it be privacy authorization or consent in general, permissions needed from consumers. A couple of months ago, I initiated an educational series where we're looking at various standardization efforts that are underway that are applicable to patient permissions and patient consent.

The first one was from OASIS, and we looked at the privacy management reference model that was initially developed by the International Security Trust and Privacy Alliance and adopted by OASIS. This is really a framework for resolving privacy policy, and it identifies the services that would be needed to really manage end-to-end privacy consent.

The second session, which was last week, was on the IHE integrating the healthcare enterprise profile called Basic Patient Privacy Consent. That's a very simple and direct profile for capturing the fact that a patient is aware of and has signed a consent, regardless of what it is. It's a CDA document exchange.

The next one coming up is May 14th from 10:00 to 12:00 Eastern time, and this one is focusing on the work of HL-7 in both their domain analysis model, and their composite privacy consent directive, which is the intended replacement of B2PC, so I hope that any of you who are interested in these sessions will dial into them. We also have invited the privacy and security policy workgroup, so both workgroups are participating in these sessions.

Now moving on to engaging patients and families, the left two columns you see there, the furthermost left column is the care goal for engaging patients and their families, and this chart shows the combination of the objectives that were identified by health information technology policy committee and those objectives that were adopted in the NPRM that was issued on meaningful use. The overall care goal is to provide patients and families with timely access to data, knowledge, and tools to make informed decisions and to manage their health. The stage one objectives in meaningful use, which we spent some quite some time two meetings ago, I believe it was, exploring where to provide the patient, the consumer, an electronic copy of their health information to provide them timely access, electronic access to health information and to provide a clinical summary of a visit.

Moving on to the objectives for 2013 and 2015, you can see that they envision the consumer to become increasingly engaged in their own care. And I think that they envision them becoming more like what John mentioned earlier, the sort of Facebook for health. For 2013, the objectives developed by the policy committee were to provide consumers with a personal health record that's populated in real time, whatever that may choose to be; secure patient provider messaging; secure e-mail, for example, between the patient and provider; educational resources; patient preferences, which includes patient permissions, but is not limited to patient permissions; and the ability to incorporate data from home monitoring devices. So we know that there's a general trend for more and more care to migrate out of hospitals and into homes. In 2013, we actually have some meaningful use measures in that arena. Then 2015, the objectives are more in the area of incorporating more decision support for consumers, self-management tools and the ability to electronically report on their experience of care.

If we look at these meaningful use measures that are anticipated for 2013 and 2015, this is an area, Dr. Blumenthal, that we don't have adequate standards, and that's very, very clear. It's not just a matter even, as Nancy mentioned, that we need to make sure we select mature standards, but in many of these areas, we don't even have immature standards.

First, in the area of electronic copy of health information, you recall we had an extensive conversation about this whether it needs to be human readable. We know it needs to be human readable. We know it needs to be readable by a PHR, and exchangeable with other electronic health records. But we don't have standards to lock down exactly what that means. What the clinical summary is, we don't have a standard for what a clinical summary for a patient is or for a consumer.

What real time means. What does it mean to provide real time? In most cases, when people refer to real time, they're really referring to that advanced near real time, but even what is near real time? Secure patient provider messaging will need to be authenticated at both ends. It needs to be private. It needs to be integrity protected, attributable, and audited.

Now we do have standards in all of these areas, but they need to be applied to secure messaging between the patient and provider. For example, if we have a digital certificate for every patient, is that realistic? How are we going to authenticate a patient?

In the area of patient permissions and preferences, I'm involved with a study right now that's looking at how different hospitals are capturing consents, and how they capture consents and privacy authorizations and informed consents under common rule, all of these vary widely across provider organizations.

How to incorporate consumer data into electronic health records, home devices, consumer reported data. I know there's been quite a bit of discussion around the integrity and trustworthiness of consumer provided data, but we don't have standards in that area. Decision support, when I think of decision support, I think data mining. When I think data mining, I think privacy, so there are definitely issues around using patient data to develop rules that then are incorporated into decision support tools.

Both the issues of the safety, how safe is it for a consumer to use decision support tools that are provided then online and the privacy? Care experience monitoring, which is currently on the list for 2015 and, finally, usability. Usability takes on an entirely different meaning when the using individual is a consumer rather than a professional.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst

All of that list is really about translating the concept of meaningful use for consumers. That's what it's about, and how the policy committee is going to begin to deal with those issues, define them, and what role we're going to play. So we're just raising that today. Obviously we all understand the concept of meaningful use is great. It's a wonderful concept, use of the term and captured our imagination. And it's, at its core, about changing physician behavior, but it's also, as that list Dixie just presented implies, it's about changing consumer behaviors as well.

We're going to actually borrow another concept that might get more widespread or overlap with the concept of meaningful use, and that's the concept of nudging. Very simple, easy to understand, made popular a couple of years ago. Some of you may know the book, *Nudge: Improving Decisions about Health, Wealth, and Happiness* by Cass Sunstein and Richard Thaler. Cass is now at the White House as senior advisor, and a lot of this thinking has filtered into a whole broad array of areas, including some elements of the health reform bill about how consumers are making decisions about insurance choices, etc.

We're just introducing that here by way of trying to move the needle a little bit on thinking about consumer meaningful use. Nudging is the nothing more, very simple concept, the art of guiding consumer behavior by manipulating the ecosystem of choice and decision-making. That's very familiar to all of us, lot's of …. Per the conversation before, policy does that. Technology also does that. All of Apple's products have fundamentally changed the way we interact. Facebook was mentioned before as well.

We believe, and no one in this room obviously would dispute that HIT tools absolutely offer a nudge, an incredible nudge opportunity in healthcare. How revolutionary that's going to be is open to question. Is it going to be just a different way like the iPod is a different way of purchasing music. It doesn't really fundamentally change the fact that you're listening to music. But other IT tools do fundamentally change the way things happen, and I think all of us in this room will believe that some HIT tools will fundamentally change the way consumers engage with the system. So we're just putting all of this stuff on the table.

John Halamka – Harvard Medical School – Chief Information Officer
Should we now be the Office of the Nudge Coordinator?

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst
Yes. I think that might be a good, yes. I think you could have a division in there, the nudge division. We've got two examples to present here really quickly today. There are many, many more. The first one is on homecare. John, you'll be interested in this.

We're actually inspired to talk about homecare by a hearing held by the policy committee, either last week or the week before, terrific panel presentations by folks from Intel. I think we all know the work that Intel is doing in the area of homecare devices. And a bunch of other folks, and Dixie and I both listened in on that and were just blown away. We knew some of the work, but there are really quite revolutionary tools coming.

Homecare, first of all, is evolving in and of itself. I mean, homecare has a long sort of tradition history. It's both a supplement to nursing homes, but it's also a replacement to nursing homes, and there's lots of new discussion about how we're going to really … point to there. Hit many birds with one stone. Consumer preference, people want to stay at home, less provider-intensive, safer than hospital nursing home, lower costs. How are we really going to make that happen in a new way?

We think HIT tools are a way that could engage patients and consumers to really want to stay at home more and enable them to stay at home more and stay out of institutions and out of doctor's offices,

frankly, etc. We're just posing the question today, what is the role of the policy committee and the standards committee in recommending standards and thinking through this for certification criteria for homecare devices, exchanges between providers and homecare devices, etc.

Back to Dixie on point two, and I just wanted to make the point here that the previous slide on homecare, that's the way I think in a bunch of words here. The next slide, this is the way Dixie thinks, much more sophisticated graphically, perhaps more engaging.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I like animation. I can't help it. What you see now are the consumer permissions that we traditionally think about, you know, the consumer's consent to send their health information to a payer, the authorization to disclose their psychotherapy notes. One of the areas that's being explored even now, that consents required to share information across, with health information exchange and an authorization for a health information exchange to use the health information in particular ways.

As we look at more increased consumer engagement though, a number of new permissions arise. Permission to exchange secure e-mail with one physician, permission to query a home medical device. I was telling Steve several years ago, I did some work for one of the companies that makes pacemakers, defibrillators, and we were developing an architecture for remotely interrogating the device and reprogramming the device. Well, obviously there needs to be some consumer interaction there. You don't want to reprogram the device while the guy is painting his house. There's a need for some interaction there.

Then, thirdly, the permission for a PHR vendor to query the home device, and then the last example I have here, the permission to use the health information to direct self-management tools. We know every one of these PHR vendors, that's really what they're looking at to make their money, is to provide these self-management tools and to push the providers towards certain products and procedures, etc. And, in order to that, again, requires some level of data mining and looking at the data that are there to determine what tools to make available to the patients, so all of these are new permissions that we really haven't thought through at this point.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst
I think we've made these points in the last few minutes. The policy committee has already begun to think through some of these issues, and our role here, which we're trying to spark the conversation today and some thoughts for the future is what's going to be the proper scope and role of guidelines and standards in this area, and regulations and how guidelines and standards differ per David's note to us about three, four weeks ago, differ from regulations. I mean, there's no question that guidelines and standards are going to be needed here, and hopefully change physician behavior through meaningful use, but also nudge consumers in a direction that we all know. But how is that going to be different from regulation? What are we actually going to put in regulation here – a very open question?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
And I also want to add that it's not only what we do, but what we don't do that will shape consumer behavior. It's not only the standards that we prescribe, but the standards that we don't prescribe as well, so we believe this is an important issue.

John Halamka – Harvard Medical School – Chief Information Officer
Just a friendly amendment to your slide five, so there are, of course, known standards for a clinical summary. There are known standards for what is your electronic copy of record. The problem here is that as the IFR is currently phrased, if an 87-year-old walks into Beth Israel Deaconess Medical Center

and says I want one of those electronic summaries of my entire lifetime health histories. You have 48 hours to produce it. And, by the way, we have 4,000-page chart that goes back to 1939, it's not precisely clear what we're supposed to do. Now if what you said was there is a standard called a continuity of care document, a continuity of care record, or whatever standard you want to pick, and the definition of a lifetime health summary is your current problem list, your current medication list, and your last discharge summary. Then we know how to do it. So I think that's what you were really getting at is we need more guidance as to what it means to get an electronic healthcare summary.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Right and we have a CCD. I don't think you're going to hand a CCD to a consumer that walks in the door, although I they want it sent to their PHR vendor, that may be appropriate. What you use when is part of that as well.

John Halamka – Harvard Medical School – Chief Information Officer
Right, very reasonable. I'm sure there are going to be many comments. Just one comment I'll start with, just regarding this consumer engagement and homecare devices, as some folks may have seen in my blog, I'm testing out a scale at home that when I step on the scale every morning, does a restful transaction to Google Health, does an analysis of my body type, my current height, decides what my body mass index is at this moment, my percent of lean body mass, and then restfully posts to Google, Microsoft, and at my, if I consent, Twitter all that information and all this happens invisibly when I step on the scale in the morning.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
And then if you exceed a certain threshold, it shocks you.

John Halamka – Harvard Medical School – Chief Information Officer
Yes. Now, David, you'll love this feature. You might imagine that in a given household, there are multiple individuals who may step on the scale, so it does a probabilistic guess as to your identity based on the likely variability of your weight. Yes, right, so it turns out that my daughter, my wife, and I have a certain set of error bars around our average weight and, therefore, it actually guesses our identities appropriately. So it has incorporated many of the standards we've talked about today.

David Blumenthal – Department of HHS – National Coordinator for Health IT
That's very important for the shock delivery.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst
And I can't wait to read how your diet may change. I read before on your blog what you were eating.

John Halamka – Harvard Medical School – Chief Information Officer
That's true, but it actually incorporates consent. Where do I release the data, under what circumstance, and that consent is by individual who could have different preferences. It has a standard for transmission, which is embracing Web standards, but it actually does have some interesting flaws, and that is that the content standards are not regularized. That is, it uses some … type protocols for using a JavaScript library, which is a usual unusual. But it also requires one company to be at the center of all the scale's transmission, and if that company ever goes out of business, the scale becomes totally useless.

And so although it's true that it can go Google, Microsoft, and all these others, there's a sort of central intermediary. Wouldn't it be cool if you got to the point where we specified every device, yes, uses these content and vocabulary and transmission standards so that the device itself could go to Google or to Microsoft or to any provider you choose to receive the data with your consent.

Anyway, let us open it up to David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Dixie and Steve, that's a great and very useful summary of one level of the issues that are at stake, and certainly agree that every one of those is really important. I want to suggest that there is still a layer below that that's at stake for a discussion as well, and so much the same way that John can be counted on for reminding us about long-term care needs, you can count on me to bring up the question of where is this data being aggregated and under whose control is it?

We have slipped into the use of HIE and PHR as if those are well defined entities. I would suggest that they're not, and that there's a cross between those two entities that I'd like to call a health record bank that is a model, which is driven as much by policy choices as by anything else, but there are technical capabilities that would match policies such that this longitudinal record that we all would like to have available to us could be accumulated in a manner that puts it in our control instead of in the control of disparate, spread out entities all around the country, and that that's something that's a cross between a PHR and the current sort of notion of regional infrastructures or regional repositories.

I think that as we start to wrestle with the convergence of policy issues around consent and control, we have to rethink or continue to think about the question of where is this data landing and whose control is it under in the first place, and what does it take to land in a place that both serves the consumer's needs to take control of it if they wish, and also the needs of the providers who need comfort that it's secure and integral data, if you will. I think there's one more bullet on your slide that goes to the very top, which is, where does this data live in the long run. Who owns and controls that longitudinal patient record?

John Halamka – Harvard Medical School – Chief Information Officer
Carol?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. Two comments, one very related to the last comment that was made. Ten years ago when I started working on health IT policy in a meaningful way, I was talking to someone very smart about consent, and I thought there was an answer. And they said to me, "Consent to what for what, to whom, with what protection?" My answer changes when you answer all those questions.

And my worry with sort of looking at consent in the diagram as a one sided issue is that the answer really depends on what's happening on the other side of that. In the HIE model, that's true. Even in simple exchange, provider-to-provider, there's somebody in the middle who is looking at that information as we're going from one provider to the other. If it does, what are the protections that are offered me? My answer changes if every one of those answers change.

Again, now I would make the reverse sort of comment that I did before, which is that this really makes clear, and I think your comment did too, the need to have these conversations in tandem where we're talking about the architectural issues, the big policy issues in tandem with the standards issues because there is a lot of specificity and context that's needed to really work on policy in a meaningful way, and similarly on standards. I just want to reiterate that point.

The second comment I wanted to make is I would modify the title of the slide with all the areas that standards are needed to say standards may be needed. I don't know that standards are needed in all those areas. And, in particular, in the case of the 87-year-old who comes to Beth Israel, I'm really worried that we're going to get ourselves into a place where we are also figuring out what is consumable and

useful and age appropriate and context appropriate in the realm of standards for the consumer to get their information.

We've been really pushing to sort of uncouple the question of electronic access and electronic download of some standard information that's human readable is step one. And then step two, and it may be the job of someone other than BI, right? But step two is how do I make that useful to somebody? How do I support them in decision support? How do I make it right for the mom who has a kid who just really wants immunizations for the kid and doesn't really want all the other stuff that might be in the summary record? How to make it useful for them versus the 87-year-old that's looking for sort of everything you know about them.

I would just encourage that the more we uncouple these questions, and the more flexibility we afford in answering those questions, the less we will encumber the whole issue of consumer engagement, which I think is a critical issue. It needs to be sort of gotten off the ground relatively quickly, and I think we can do that if we don't assume that everything necessarily needs a standard for the EHR that's certified, but rather that everything is in some format that someone or something can make use of.

John Halamka – Harvard Medical School – Chief Information Officer
Just a comment on consent, there's a wonderful white paper that has come out of ONC that looks at a framework for consent, and it's not trying to solve the problem, but it more or less identifies what are the flavors of consent in use in this country, opt in, opt out, opt in and out with restrictions, etc. I just think you've made the comment. We've all made the comment that when you have a policy framework that can constrain the standards that you have to use and, boy, it would be nice to have a finite number of consent possibilities for which standards have to be chosen. Good. I think Jim was next, then Wes.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Jim Walker – this area is going to be an interesting one in terms of understanding, I think, kind of what Carol was saying. What standards are in fact needed, and in what order, and how simple can the standards be for us to get started, and how can we have a rational plan for making those standards more and more subtle, as our use cases develop, and as we get more demanding about the kinds of things we want to do with this information?

If you go back to that list of tasks, we and other organizations in this country are currently doing practically all of those, getting weights from patients and running care protocols based on them, you know, automatically on scales and all of the rest of those things. And obviously we're doing that in the relevant absence of standards. And so I think one of the questions is how can we do? We send clinical decision support direct to patients, and they, if they want to, act on it, and get a closed loop, sort of end of the process, and may never be in an office of any sort during that whole sub-process. And so I think one of the questions is how is that being done now, and what is the minimum that's needed, and then what are the next set of things that would enable us to take the next set of steps? I think we can get a lot farther, a lot faster, with a lot less fuss.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm sure you would only tweet your weight in order to advertise the benefits of the ….

John Halamka – Harvard Medical School – Chief Information Officer
There you go. Carol and I are joined ….

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Is Carol going to Tweet her weight too?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
No.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
My mother would be upset.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So you haven't friended your mother on Facebook either. I just have to say that serving in this committee for a year now has had a profound affect on my view of standards. I've become a reactionary. And probably the pivotal thing for me in that change has been around this issue of standards for policy and consent. And it has been because we have a tendency as technologists to say we can finesse the policy by building powerful standards that can express any policy that you need in them. And when those guys figure out the policy, we'll be ready.

And so we build, in the abstract, without this feedback loop of actual usage, standards that with no deprecation of the standard itself, in fact no inspection of the standard itself, I shudder at implementing because I say can I imagine 1,000 hospitals getting an explicit, unambiguous statement of their privacy policies that a coder can put into XML? I can imagine that, but not while I'm alive. Not that I'm against it, it's just I think I'm going to die sometime.

So I urge us to follow an approach that's been hinted on in some of the other comments or made in the other comments, which is, look at what's being done out there. Look at what's the minimum that's necessary to be done, even if it means we are promoting the standards that have to evolve over time. For scales, for example, I am happy to know that one of the healthiest people I know who weighs every day, but when you look at the use of scales for congestive heart failure patients, then the same technology carries a whole stronger implication.

And Palo Alto Clinic, I don't know if they're doing scales, but they're doing glucometers. They're doing other devices using a commercial firm. And the commercial firm handles consent. It handles dealing with multiple device manufacturers. It handles taking that basic data stream and working it through a workflow or a clinician can take appropriate action on it and things like that. I don't know that we want to insure that John will have to replace his scale too early before we have the feedback from those private companies on what are the real issues we have to standardize and things like that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
With respect to the consent, I totally agree with you. I think the consent area is in danger right now of getting overly complex from the policy side of things. And I would particularly point to segmentation, which is one of the ARRA 8 that you have to address segmentation. And if you look at HIPAA, it already has the requirements for segmented psychotherapy notes, right? But the way segmentation is being interpreted is give the patient the right to segment out anything that can be denied this doctor. These three data fields can't go to Dr. Halamka. And I think that's where you get into a lot of trouble in exactly the area you're talking about because the policy is bringing forth a need for a level of complexity in the standards that's beyond what I think is even safe.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Can I respond to her response? I'm not going to say what he said to her, but several points about that. One is that if we just think of the human time that would be involved for clinicians in figuring out how to deal with that, it's got nothing to do with how our reaction to the standards are. I think that we also need to examine the proposition that the data that gets transmitted carries the policy restrictions associated with the data, which is in part of that same thing, and just implies a whole lot more about what you have to do in your evolving legacy system in order to deal with the data that then you had before.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks. Steve Findlay?

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst
At the sort of level of government functioning and this committee's advisory role to that, I would recommend that we think, but also ONC think, in terms of what other regulatory agencies do and also in ONC's relationship with CMS in the implementation of the first batch of regulations. I'm most familiar with FDA. It's 50, 60 years of organic development in standards, guidelines, regulations for FDA. Frankly, most of the structure of the drug approval business these days is not in regulation. It's in standards and guidelines. FDA issues a new guideline practically every month of very specific nature.

I just put that out there. Don't want to go on and on because we all know FAA, every single federal regulatory agency has its own sort of structure. But all of them probably are consistent in primarily operating through standards that have come up organically in the world or set by the agency. In the case of FDA, the industry begs for those guidelines. They beg for them, and they get them because it's so critical to their mission to get that drug approved.

Now it's a different template for HIT, obviously, but per David's missive, which I think everyone remembers about the difference between regulations, standards, and guidelines, and what you actually put in regulations, etc., this just strikes me very, very key because I see ONC and CMS evolving. The stake is in the ground now, evolving over the next decade to be mostly issuing guidelines and standards or preferences for them and not regulations, but we'll see.

John Halamka – Harvard Medical School – Chief Information Officer
David, any comments you'd like to make on that issue?

David Blumenthal – Department of HHS – National Coordinator for Health IT
No, I think those are very wise observations. There is a history, I imagine, of legal rulings, as well as, and practice that may give guidelines and guidance in some regulatory agencies, and almost regulatory standard. We are going to be feeling our way. We have, right now, though, the requirement to adopt standards in regulation. And also, the requirement to certify records against certification criteria, and so there are implications that we have not fully explored to adopting standards and certification, and then their implied certification criteria in anything other than regulation.

It means that we will not be able to certify records against those standards except in, well, I don't know. I mean, we haven't thought through what that means. You could imagine all kinds of other things that could be done that are not certification in the formal sense, but advice or observations, opinions, how they will impact the market. I don't think any of us have explored, but it's the idea of flexibility is certainly something we're acutely aware of and have struggled with and will continue to struggle with.

John Halamka – Harvard Medical School – Chief Information Officer
David, did you have another comment?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes, to pick back up on a couple of threads that have woven through this conversation. One, Wes' point that I think he was trying to say is don't let the perfect be the enemy of good enough when it comes to some of these standards around consent. To that end, I would urge that any of you who haven't established a Facebook account and played with your privacy standards in Facebook should do so to understand both the complexity of choices that are available for data that is arguably less sensitive than our health data, albeit depending on what's in your pictures, maybe not.

But also, to see how it is in fact quite possible to put together a consumer friendly, user interface that does in fact give you a phenomenal amount of control over this sensitive data, including what I just discovered in playing with it the other day, tools that let you actually mimic the person who you are trying to control access to to see what in fact they could see if you were them, so it's really very powerful, even though it is quite complex. And the key win there is that it's my choice. It's not imposed on me by some external standard that says you get to control these things, but you don't get to control those things. Now the downside is it's a proprietary vendor, and they can change the rules at any time. So I think there's a balance, particularly around health data that is somewhere in between the complete, sole source control model that Facebook is, but there's a ton to be learned there from what they've done. It's really quite impressive.

Then the second thing is maybe I think picking up on something Carol said, or maybe I'm just thinking of an idea here. Back to this notion of, John, it's actually picking up on your idea—I'm sorry—of what do you do if someone who requests a 4,000-page medical record. I heard a really fascinating presentation by Bill Stead from Vanderbilt a couple of months ago where he argued that in terms of documenting clinical encounters, what we should be doing is preserving the raw data of the encounter and then applying clever tools to extract out of that the summary information that's necessary based on what we know today, but preserve the raw data so that someday you could go back and extract additional data based on new learning.

So you may not have realized a certain bit of history was important in the past, and if you were using a structured tool that forced you to only document things that we think are important today, that bit of history is gone. If you capture the raw data in the form of, say, a conversation, you can go back and extract out and listen to it again. And it's not infeasible to do that anymore. A terabyte of data costs about $100, and I'm pretty sure that the entire raw history of all my encounters from my pediatrician onward would fit easily in a terabyte of data. So for the technical cost—

Pardon? I mean, even images. I haven't had that many images, so I recently had a medical issue that actually related to something that happened to me when I was in college, which, of course, I have no records of that encounter, but it really would have been extremely valuable to have the rhythm strip from the emergency room visit that happened to me when I was about 21 years old. We could do that if we just had an automatic way to put the raw data into something that we could control and then process increasingly cleverly as we build better tools over time and that the technical cost is actually pretty inexpensive now.

John Halamka – Harvard Medical School – Chief Information Officer
Very good point. In fact, just to give you some data, so I oversee three million patient records, and it's all the images, all the EKGs, all the text. On average, we add 80 Megs per person per year. It's pretty de minimus. Now that's recognizing not everybody gets an imaging study every year, so that's why it averages out as such.

One other comment about consent, I think this is going to evolve, so when I look at the PHRs that I use personally today, I can invite a clinician to see my PHR and de-invite them at any time, but at the moment, I don't have the granular control of what they see. It's just I invite them or not. And I am sure such features will be added, as we get segmentation. Facebook didn't start as complex as it is now when they first launched their system.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Right.

John Halamka – Harvard Medical School – Chief Information Officer
My daughter, by the way, is applying to college, and I've warned her, pictures are forever.

W
In terms of going back to what we should help you advise for that, there are, I mean, well, David McCallie's issue, I'm collecting over a terabyte and a half per month in my databases on 9.6 million beneficiaries, in fact, maybe more. The key issue on that is, yes, there's this notional issue. You could collect everything virtually forever. The question is, you're not going to retrieve everything in real ….

One of the big decisions you have to make is the time value of data. Physicians are … recent data is much more valuable than old data, and the predominant family practitioner is not going to go back and want to look at 20 years of data. He wants to see what happened that was relevant in terms of your active care. So I think we are addressing right now the very real issue is there is expensive retrieval or there is cheap retrieval because of that. You can store as much as you want, but you really need to think about how you're going to plan keeping that data, and what's the value of retrieving really old data unless you're doing once in a lifetime kind of research things.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
…if you just dump it into a directory structure and have no tools beyond the listing of the files, that's not very useful. But I'm talking about data that can be analyzed with appropriate tools.

W
Yes, but you have to make policies in your organization, again, because it is very costly to have near real time or real time retrieval of such information. A doctor, if they're in the middle of a care, waiting more than ten seconds is forever.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I'm not talking about the EMR or EHR that is used for real time care. That's a completely different entity. But I'm talking about access to the information, including summarized data that's put out at the end of the last encounter, which would be easy to get to if you want. So we have tools that go through use natural language parsing, analyze, find the concepts, structure them, rank them by value according to where they occurred in the document, sort them according to how frequently they incur, diminish them as they age out, and that's work that's doable today. And so you can literally type a query and get the important stuff, even if it was from 50 years ago.

Now that's not for routine care. I mean, I'm not suggesting that that would be what you would use for bedside care.

John Halamka – Harvard Medical School – Chief Information Officer
And there are technical means to solve this, so for example, we—

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes, there's technical ways to solve it.

John Halamka – Harvard Medical School – Chief Information Officer
…of data, and archival of data, but it's always retrievable.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Right.

John Halamka – Harvard Medical School – Chief Information Officer
I know we're running short on time for our quality, so are there any final comments that you had on that?

W
We can address the issue of, I think we should do better education on what would be a clear summary for an 84-year-old woman, whatever it is, and start publishing, I'd say, real copies of what you expect. My impression is it's the information you fill you every time you go to a new doctor on that little clipboard. And if you say that that's going to be what people should expect to get if they want to get a care summary with your histories and your surgeries, that to me would be a good educational effort that we could manage, set expectations, or set expectations to say here's five options. Let's see what consumers want. That's all I'll say on that.

John Halamka – Harvard Medical School – Chief Information Officer
Very good. A very rich discussion. Dixie and Steve, I thank you very much for raising all these consumer issues. More to come, and certainly, as we think about the domains of work that we are going to have ahead for 2013 and 2015, the whole consumer suite is going to be a very important one.

I know we have a hard stop for many people for lunch and for a conference call, so let me turn it back to Jon, and we'll hear from Janet on the quality update.

Jonathan Perlin – Hospital Corporation of America – CMO & President
And Floyd Eisenberg, I think, is going to join as well. Thank you, Janet and Floyd, and members of the clinical quality workgroup.

Janet Corrigan – National Quality Forum – President & CEO
…couple minutes to update you on the recent discussions of the quality workgroup, and then I thought I'd ask Floyd if he would update the group just on where we're at with retooling. You might want to know the progress that's been made in terms of the current measures that were elicit in the NPRM and where we're at with getting those ready to move forward.

The quality workgroup had a call last week, and we kind of mapped out what we're going to do over the next month or two. As you know, just to refresh your memory, we work very closely or very dependent upon the policy committee, which essentially lays out the framework, the priorities, and the measure concepts, and then turns to our workgroup to identify specific measures that will be used to operationalize those concepts. We're waiting to hear a bit more from them about what they expect or think would be best in terms of 2013 and 2015 meaningful use measures. And we thought, in the meantime, what we would do is to try to gather some information about what's potentially feasible in terms of measures for 2013.

It takes quite a bit of time to develop measures, to test measures, and move them through the endorsement process, so it's probably not feasible if we're talking about 2013 measures to actually work

from scratch here from the very beginning. Indeed, it may be that there are good measures out there in more sophisticated environments and environments that have experience in using HIT for a number of years, and we want to learn from those groups.

We thought one option for moving forward would be to identify e-measures that are currently in use in healthcare settings. They're being used for quality improvement and public reporting purposes, and these would be healthcare settings that have had electronic health records and personal health records for a number of years, so they're probably pretty advanced in terms of their use.

What we're proposing to do is a limited environmental scan, essentially to go out to these organizations, a limited number, to ask them for two things. We don't want their full list of measures that they're using, and I want to thank John Halamka, who shared his full list with us, and we've had a little bit of input from a couple of other members. But what we really probably want to do because we had limited time and limited resources to devote to this, is to be very focused, both in terms of which organizations we go out to in this limited scan, but also to ask them really to use their judgment and identify measures that fit in, a limited number of measures that fit into each of these two categories.

First, to identify e-measures for which HIT tools play a particularly important role in facilitating rapid improvement. For example, what are some of those areas where if you get the electronic health record in, and you're using it properly, you will see a real difference in the care that you provide to patients and the results the patients get as a result of that care that is provided?

Where is the biggest bang for the buck so to speak in terms of getting better health for patients as a result of HIT? Where it happens mainly because of the HIT enabling tools. An example, there may be medication order entry systems or things related to meds alerts, and I want to thank Jim Walker because this is really his idea to focus on these areas. He helped us think through this. So, Jim, feel free to add in your ideas here as we go along.

But then the second category are to identify a limited set of e-measures for which HIT alone is not adequate to facilitate improvement, but rather, really will require significant workflow or care process or redesign, or significant behavioral change on the part of the patient. So I think probably an example there might be a measure of whether or not some of the measures that we're actually going to be hopefully using in 2011 of body mass index, but it's a long ways from going from recording body mass index to actually getting change in the patient's health behaviors to achieve a better body mass index weight.

This would be ones where it's really not the HIT alone that is the facilitator. It requires a lot of other things to happen. And it seemed like probably for 2013 where you really are easing people into using the EHRs and the PHRs, you want to go where you get the biggest bang for the buck in terms of immediate improvement. Obviously where we want to be longer term, 2015, will clearly be to tackle all those areas where significant workflow redesign is required to be able to accomplish what you want.

We thought it would be a good idea to go out to the limited number of groups and perhaps starting with selecting the organizations that are really represented around this table by virtue of those who are members of the standards committee. And this is essentially the groups that are here at the table, to send them a request and get this initial information, and that would sort of be the first step. We would then synthesize those results and post them for public comment because this isn't meant to be limited to only those here, only it's really to be for practical purposes, that's really what we can take on at this stage. But through public comment, would have an opportunity to get input from other groups out there that may have very useful suggestions and, indeed, I'm sure they will.

We would then share those results with the HIT Policy and Standards Committees, and it would help us to just increase the pool of candidate measures that we can choose from once the HIT Policy Committee's priorities for 2013 come forward. And probably also by sharing some of these ideas, it may be that it stimulates some of the thinking of the HIT Policy Committee as well in terms of the particular areas that they identify as the best ones for 2013 and 2015.

Then, of course, having done that, it's one thing to have a measure that has been home grown within a particular establishment and used there, but we also then have to identify a process for bringing that measure forward, getting it in through the endorsement process and the standardized retooling processes, which have been developed really over the last year for processing of this first set of measures. Now I neglected to mention that we also thought it would be useful, in addition to the particular healthcare provider organizations around the table, to reach out to two or three of the leading vendors as well because they may have some of these homegrown measures that they've really built into their systems too.

So that's really the next steps that we're proposing to undertake. Jim, did you want to add some of your thoughts because you've been so active in this area?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
It's a great summary. Thank you, Janet.

Janet Corrigan – National Quality Forum – President & CEO
Floyd, why don't you give us a quick update on where we're at with the retooling?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Sure. Thank you, Janet. As far as the retooling, as I think many of you are aware, we were asked to have 110 existing measures retooled into an electronic format. For that process, we created a prototype-authoring environment. Forty-two of them have now been retooled from three measure developers, primarily AMA, PCPI (Physician Consortium for Performance Improvement), and NCQA, the third measure developer with one of the measures as Quality Insights of Pennsylvania on BMI, although in children.

We have now delivered the preliminary format of that to CMS, and we're in discussions on some format changes, so they can decide on publication. They will subsequently be placed into the standard, HL-7 standard, e-measure representation of HQMF, which provides a more human readable form than the spreadsheet output that we have today. But that has been done. We're in the process of doing the others with a lot of effort in rethinking where the information should be in routine clinical care, let alone EHR, as opposed to just what's available in claims and how can we use a claim as a surrogate, so going back to where is the information in a clinical record. I guess that's an overview, so we can open up.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let me thank you and other members of the workgroup for terrific input. Just one observation, and perhaps stating the obvious is that the opportunity to use an e-version of measures currently in use serves as a very visible way of validating the behavior of that measure in its electronic form, and I think that also helps to improve the transparency, comfort, uptake of the electronic use of those measures, so it seems like a very rational, straightforward path. I see some cards going up. Carol Diamond, we'll start with you.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes. So I think it's fair to say, of all the areas we discussed today, the stakes are highest for this one. And I say that because if the meaningful use incentives are truly this one time incentive for improving quality and interoperability, the artificial incentive, I think, was the word that Wes used. Then getting this right matters a lot because it is really the big lever here. So I'm pleased to see that there's a recognition that the current process for the development of measures in the approval just doesn't match. There's an impedance mismatch with the timing that's required, and I like the idea of going out and looking at what's available.

I just want to offer one friendly modification, which is, it's really, really important to identify those areas where there is a priority on getting something. In other words, if interoperability, you know, one of the areas of quality measurement that we identified even a year ago where there isn't a lot even being used by systems that aren't really focused on transitions of care, for instance, is in that area. There's no real sort of measurement of whether or not information is flowing from one care setting to another, from one provider to another outside of systems, and those are the kinds of things that I think will make or break whether this is truly an artificial incentive.

So I would just caution that it's good to look at what's out there, but this is a once in a lifetime opportunity to say we have some goals here on the health improvement front, on the outcomes front, on the interoperability front that we're really in search of. And if that if they don't exist, maybe we flip the process also and ask some of these organizations where there are measures being used to work on them because it may be a quicker way to get to the end result.

I would hate to see us, and this is true for technology too, I would hate to see us sort of settle for what's in use today, either on the quality measure side, or on the technology side because there's a lot of money behind sort of getting us finally in quality to the place where we have measures that matter that are outcome oriented that value interoperability and sharing of information, and I wouldn't assume that we're going to find a whole lot in some of those areas either from meaningful use or health reform goals for that matter. So I just would encourage a little bit more balance in the approach.

Janet Corrigan – National Quality Forum – President & CEO
Yes. I agree with you 100%, and I think it's important to view this particular effort in the broader context of the other activities that are going on. This is just one focused effort out of quite a few. But I agree with you wholeheartedly. It's important to have those priorities and goals more explicit.

I do think, though, if you look at some of the selection of the organizations is critical here, but if you look at especially some of the ones that are here that are clinically integrated systems, I mean, I talked a lot with Brent James. I know much of what Intermountain is doing. I have a good idea on some of what Kaiser Permanente is doing and others. And they really have started to make some very real inroads in terms of the transitions and the care coordination.

The one thing that we do start to think when you look at some of the measures coming out is the key difference between those and the ones that are in the portfolio of national measures is that denominators become defined by a set of encounters over a period of 12 months typically as opposed to the much shorter timeframe. So you do move into a different structure of measures. It's clearly looking more longitudinally and on the chronic care. So I'm hopeful that actually that some of the measures that we see from those systems that not only have more advanced HIT, but that are clinically integrated. I think that's probably just as important has having the HIT in place, will be ones that map over to the national priorities that have been set by the National Priorities Partnership or by other groups, for that matter, that will have a lot of similarity in terms of looking at care coordination and the issues related to chronic care to a great extent, so we may see some of that.

Now there are other activities out there, and this is another area where coordination is critical. The health reform legislation does provide $75 million a year for up to four years for AHRQ and CMS to put out for the development and maintenance of measures and retooling. The problem is that the appropriations have not been made for those dollars, so I think we all have to be realistic about how fast that's going to happen. There is an effort underway, a quite extensive one, that NQF is sponsoring to develop a measure agenda, an agenda for measure development and have ready to deliver at the time that those dollars start to flow.

One of the streams of input into that is for an expert panel to think through potential meaningful use measures further out. So there are quite a few activities there, but when we start talking about 2013, it's not far away, so these kinds of efforts that I know are quick and dirty, I mean, I wish that it was much more extensive. But I don't know another way to try to fairly quickly enhance that pool of available measures because I personally don't think it's that realistic to expect that we're going to start to see those dollars flow, targeted towards the measure development.

Now it may be that some groups, if we have particular ideas or identify particular gaps … various groups out there and organizations that would be willing to just do it on their own and bring them forward, they still do have to go through a process of being evaluated, and they're going to have to be retooled using the standardized approaches. Otherwise we're going to have measures that aren't harmonized and haven't been retooled using standardized approaches, so those things do take some time. They can't happen in three months or six months, so that's why we're pursuing multiple approaches.

But agree with you wholeheartedly. I wish we could map it all out from the very beginning. These are the most important areas, and here are the measures we had, the ones that we need. Get the dollars out. Development them, evaluate them, and move them forward. But unfortunately, our timeframes don't quite permit that kind of a process in whole, but in part.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Well I would just say we've modified timeframes and other processes in the area of standards. Certainly the clock ticking in here is always on our mind when it comes to standards and provider adoption, and EHRs being ready to achieve meaningful use, even for 2011. And I like the way you frame this, which is the process doesn't match the requirement. And I just think we should keep pushing ourselves to think that way because after 2013, it won't matter that much. The incentives are going to sort of tail off, so this is the moment.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
John, can I just respond quickly?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Yes, Jim, please.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I think the other thing to say, Carol, is that the assumption here is that, first of all, the existing e-measures have been based largely on quality of evidence, morbidity, mortality, healthcare impact, and the value of measuring how you're doing across … of care. And all of those filters we intend to apply to this set of data that we identify. It's just that we'll know that as we run those filters against this, it is stuff that someone has used, and so there's a likelihood you could get it into EHRs rapidly. So it's just one filter of the many others that you're absolutely right about.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. I just want it to be driven by those goals as opposed to what's available or what's ….

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
If it isn't available, we can't do it in 2013. That's one of the criteria. So you think of it as, there are eight criteria for something we're going to use in 2013, not just one, but one of the criteria clearly has to be, is it feasible? And then the others are, would it matter, and will it help us get where we're going?

Jonathan Perlin – Hospital Corporation of America – CMO & President
The cards up are up for a number of people, so let's take a last comment from Wes, and then let's make a couple of notes as we adjourn for the break. Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes. In terms of this urgency issue, I just want to say that if we had a few quality measures and a few groups of healthcare organizations use that to meet pilot programs for accountable care or patient centered medical home, we won't have lost the incentive. We've just kind of lost our ability to compel rapid adoption. We then get to the real incentives, which is where we're all trying to get, I think.

Jonathan Perlin – Hospital Corporation of America – CMO & President
That is exactly the point that I was thinking about that I know that there are some mechanics of how things operate. But, boy, I mean, to me, the prize that ultimately supported this, not just using these measures as a test of the capability, but in fact substantiating the capability for interoperable healthcare with the characteristics that David described earlier. And I also appreciate Jim's comment that in fact that trajectory is also, to the extent practicable, that is applicable, and given the constraints of the world around us, important in a broader thinking, such as the National Priorities Partnership and given that direction. Janet, maybe a last word on that.

Janet Corrigan – National Quality Forum – President & CEO
One last comment: The incentives actually don't go away. They just take a different form because the legislation is chucked full of payment incentives and, boy, the ante goes up and up over the coming years. And it's really the same measures that are going to end up being used in the payment program, so I think we can expect we'll continue to have it, but I do hear, I think, Carol's cautionary note. Let's make the most we can out of 2013. We do also want to do that, but we can continue to ride with other incentives too.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Absolutely. I think, for all those in the ecosystem that aren't thinking about that ecosystem and how it operates with a new set of incentives that is really not just implicit, but increasingly explicit. These don't go away and, in fact, will require the framework that this develops.

Terrific conversation. It does take us back to the initial framing conversation of the interoperability and the framework that's implied in some of the work ahead. After lunch, we'll come back, and we'll hear from the clinical operations workgroup, the vocabulary taskforce, recommendations on that, and then Doug Fridsma will be back to talk about some of the NHIN Direct experience and then the great work, great updates from DEA.

So it is 12:37 now here, I'm sorry, 11:37 here on the East Coast. Let's break until 12:30 sharp and reconvene at that time. Many thanks to all for your participation and hard work.

Judy Sparrow – Office of the National Coordinator – Executive Director

Could you take your seats, please? We're ready to resume the meeting. Hello. We're ready to resume the meeting, please. Thank you. Dr. Perlin?

Jonathan Perlin – Hospital Corporation of America – CMO & President
We're going to go ahead and get started again. Thank you very much for coming back and starting promptly. Jamie Ferguson, you're here. Is Betsy Humphrey presenting virtually?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
No. Betsy, unfortunately, is unable to join us for this meeting, so I'll be doing the presentation.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific. I want to thank you and John Halamka for the ongoing work, and you and Betsy, in absentia, for the work that you'll present today on vocabulary.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great. Thank you very much. The vocabulary taskforce of the clinical operations workgroup held public hearings into the governance of the value sets and subsets for vocabularies that are required for meaningful use. We focused both on the particular value sets that are required, such as the quality measure value sets that describe essentially the entire universe of terms or concepts that are required for, in that case, the numerators and denominators for quality measure reporting, as well as subsets such as the most frequently used codes or the most frequently used terms and concepts in each of the different controlled vocabularies that would be a starter set for implementers as part of their implementation toolkit.

There are other kinds of subsets that we also discussed and focused on, such as clinical specialty related subsets, the codes that would be used for a particular clinical specialty for orders, as an example. And so we focused these hearings and public input on mechanisms and requirements for governance of these things within meaningful use with a focus on stage one of meaningful use. And so we've reported back the early findings, I think, in the last meeting of this committee, and we're now here to discuss our two recommendations that we have as a result of those hearings and that previous discussion.

Our first and really the central recommendation that we have comes from, I believe this was an almost perfectly unanimous opinion of all of our panelists and witnesses. Now they may have used slightly different words, but wherever they talked about governance authority, we heard from pretty much everybody that a single central authority needs to be established to coordinate the creation and dissemination, and to make available the value sets and subsets for meaningful use.

And so we've spent quite a bit of time fine-tuning the recommendation that you see here and in your package, including a couple of last minute wording changes that resulted in a handout that's in your packages here today, but we recommend that a single federal officer agency should have responsibility to insure the creation, maintenance, dissemination, and to insure the accessibility of all the vocabulary value sets and subsets related to meaningful use. So this would include those value sets that are required for meaningful use, for example, for the quality measures, as well as those that are related in terms of the convenience of implementers.

We recommend that this entity should have responsibility for coordinating across other federal agencies, the relevant standards development organizations, and other stakeholders to identify the value sets and subsets that are needed, who will produce and maintain each set to determine the appropriate dissemination schedule and update frequencies, to establish standard formats for both the production and dissemination of value sets and subsets, to manage the review and approval processes, and also we

have a subsequent recommendation about infrastructure. But we recommend that this central authority should insure the existence of authoritative infrastructure for the value sets and subsets. And we also heard from many of our witnesses that education, communications, and outreach is very important, so we wanted to make sure that there's a responsibility here for insuring that those things occur in relationship to the vocabulary sets.

We also heard from many of our panelists a desire to overcome licensing issues with regard to the vocabularies that have been established, and there's a lot of support for what's called the SNOMED model in which, in essence, the vocabulary is made free to all the users of it across the United States. In fact, several of our witnesses used exactly the same words in saying that it was critical that the central authority needed to have both the legal authority to coordinate these matters, as well as funding to provide licensing for free U.S. use of the required vocabularies. So those are the key components of this recommendation are the coordination aspects, as well as funding of the required vocabularies.

A point that came up on our last workgroup call on this is that there may be some cases in which the value sets themselves would require licensing, not just the underlying vocabularies, and so the recommendation for funding would include any licensing that's required for the value sets themselves, as well as the vocabularies. With that overview, I'd be happy to take questions or a discussion on this recommendation from the committee.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Everyone is just shaking their head.

W
Everybody is supportive.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. So….

John Halamka – Harvard Medical School – Chief Information Officer
…one comment, and that I probably said in previous meetings that I have a team of developers inside my organization working on all the various meaningful use transactions, and they came to me spontaneously and said, "So where do I download all the value sets that I need to make these things happen?" And, of course, what I did was I went to HITSP resources, FDO resources, National Library of Medicine resources, and assembled a list of 17 different URLs. Wouldn't it be wonderful if there was, whether it's USHIK or PHIN VADs or whatever other infrastructure we want where folks could get these? They were definitive. They were updated and maintained.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
No, I'm sorry, David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is just a hearty thumbs up. I have a recent use case experience, just like John's. One of the teams inside Cerner that was working on a product came to me with what they thought was just a simple question of we want to capture the patient's allergies. What code set do we use for allergies? And I said, "You have no idea how hard a question you just asked." And it's just a nightmare, so we need to make that a lot easier.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Now one of the things we had a fair amount of discussion on was the fact that there are different federal offices and agencies that have specific legal responsibilities, and that some of the vocabularies that were in the IFR that have been selected for meaningful use have legal requirements in terms of their schedule and so forth that are set outside of ONC. And so, in those cases, we would say that this central authority should have a coordination function. But, to the extent possible, we would recommend that this new or existing federal office would have the ability to control the schedules and the manner of dissemination of these things.

So we removed the word "control" from this recommendation and where it had previously appeared in previous drafts in many places, in recognition of the fact that there are different agencies and offices that have different responsibilities, different charters and missions that have to be respected and so forth. So we made it much more of a coordination function, but the intent here is to have a central governance authority for everything that's related to meaningful use.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great. Walter?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes. Just a question about the scope: I think there's, I mean, traditionally vocabularies and the way one can think of them is really related to clinical type clarification of information. But thinking more broadly, I think there are vocabularies that relate to other fields, other areas, particularly, for example, security and privacy, particularly privacy. So vocabulary or value sets related to privacy, for example, the clarification of purpose of use or things like that. Are those part of the scope of this recommendation that there should be a single point of access to …?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, the focus of our hearings was on the clinical vocabularies, but I think that the other ancillary vocabularies should be included in this even though they weren't the focus of our hearing.

M
Just to reiterate the previous conversations that we've had … as well … stating the obvious here. This is obviously very closely tied to what the work that's being done with the quality group because if we're going to be able to measure quality in this organization or this recommendation would be one in which they're establishing the value sets. Getting back to Carol's point made earlier, we've got to make sure that we're tightly integrated in these recommendations, but also the recommendations of the types of quality measurements that we're going to be looking at since we don't want to recreate the wheel on the quality side if we're going to get this implemented by 2013.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Absolutely true.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, and just to reiterate, the recommendation here is about governing the processes, not about governing the actual creation, so we're not recommending that this central authority would actually perform the creation of the value sets or actually even manage that, but would govern the processes by which those things are accomplished.

M
I see.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Just to reemphasize your point, so when you ask, as Floyd … there he is. He's driven crazy if you say, here's a numerator, and here's a denominator, and you have a choice of 17 different vocabularies for each of these. And so, Floyd, certainly, if you want to comment on how it is important to have a constrained set of value sets for the definition for numerators and denominators in quality measures.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Actually, I appreciate the ability to comment on this because, in the retooling effort, that's exactly what's been happening. It's also been interesting where there are some terminologies that are proprietary, so we are able to see codes, but not descriptors because they're proprietary. And to know that this list of codes all applies to the same data type that's in QDS or the same context of use, we actually need descriptors. So we're actually going out and looking them up to make sure, and we're finding sometimes they need to be split.

It's a very complex and time-consuming issue to do this. And I think, with some governance and availability of this kind of information, it will certainly make it easier. Many of these are reusable. Some are not, but the more they're available and open, and there's governance around it, the more it's going to enable this process for measurement, as well as routine use. The same thing that identifies the right procedures for a measure are often the same procedures that would be in decision support as part of the order set or whatever offering there is in decision support. They would be reused for that, and we're finding that, in a decision support panel, we'll be coming out with a model there that actually uses all those same elements and same value sets.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Good. Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I just wanted to address Walter's point, but I agree with Floyd 100% that the consistency of the value sets is terribly important. But, Walter, when the providers were polled informally in the context of these hearings about, well, would they want to get data from the source? Would they want to get them for purpose specific reasons from here or there? The unanimity among the providers of healthcare that they wanted one place to go to get what they needed to do their work was overwhelming.

The answer to your question is, yes, if those value sets are needed to conduct healthcare and maintain interoperability, then this organization, ideally, may not be the owner, clearly not, may not be the developer, but better darn well have access to the most current copy and that the community would have confidence that they are current, up to date, and timely with the availability of these resources.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think that goes directly to recommendation number two.

Jonathan Perlin – Hospital Corporation of America – CMO & President
David?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Sorry.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

…to put a comma and on the end of Chris Chute's eloquent statement, and that there not be odious licensing complexities in the way of their use because, if there are, people will just bypass them and do something else.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Our second recommendation builds straight off the first one, and our intension actually was to focus first on governance and then get into infrastructure, which we still plan to do in the taskforce, and so the work ahead of us does have to do primarily with tooling and infrastructure as a next step, but we couldn't avoid this central recommendation coming out of all the public input that we heard in our hearings.

This recommendation is to establish authoritative infrastructure for the development, maintenance and dissemination of the value sets and subsets that are related to meaningful use. In essence, what we're seeking and what we're recommending is one stop shopping. This goes to all the comments that we've heard around the room here today. The implementers and users of the EHR technology want, need, and are demanding one stop shopping for the meaningful use vocabularies. Therefore, we're recommending the establishment of a central repository, a central download capability, and a central feedback loop mechanism in the federal government for the dissemination of the meaningful use vocabularies.

At the same time, we did hear a significant minority view, if you will, recommending distributed, not a centralized repository. We did hear from a very clear majority of our witnesses promoted the central authority. And all the providers and users wanted just one place to go. But we also heard, I think, a significant viewpoint that other decentralized alternatives should also be enabled. And so while we do think that the large majority of users and implementers want to have one place to go, from the viewpoint of the producers and the providers of the vocabularies and the value sets, they also want to be able to maintain their alternative distribution mechanisms. And there may be users and implementers who find that they want to go back to that source and not to the central authority. So we also recommend enabling decentralized, public or private sector alternative repositories for dissemination that may have different distribution mechanisms. They may have alternative update frequencies and schedules that could be worked on a separate basis outside of the central authoritative framework.

We also thought it was very important to differentiate in this context between the specific value sets that are required for measure submission for meaningful use, as an example, so that those things that are absolutely required versus a more open, looser control over things that are convenient for implementers that might be shared. They may be vocabulary specific, or they may be vendor specific, or they may be specific to a particular community of users. But there may be different, for example, frequency based subsets of the top 90% or 95% of lab test names as an example that's frequently used in terms of a subset that you'd want to have made available, but you wouldn't want to necessarily constrain with tight controls. So we're recommending differentiation between tight controls as those things that are required to qualify for meaningful use, versus looser control over the subsets that are really for the convenience of the implementers and the users.

We also thought it was important, and we also heard a lot of input around making the vocabularies searchable and discoverable by the end users of the EHR systems. This is not the same thing as the research based searches that UMLS, as an example, is very good for today. So for researchers, there may be fine toolsets that require a great deal of sophistication, but the end users of the EHRs, the clinicians, also need to have the vocabularies searchable and discoverable. And so we're recommending establishment of open, public, consensus based processes to determine and standardize parameters for that tooling that would make the vocabularies more useful and more usable by the end users of the EHRs in their clinical settings.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
My just two comments there: I received an e-mail from somebody who said, I understand you need NDC codes for e-prescribing. Are those available on Google? Illustrating the problem. Secondly, somebody said, "I've been using my EHR, and I think the ICD-9 codes are wrong. How do I check?" This is sort of the issue. No one knows where the source of truth is to be found. And it may very well be that the codes are altered with various English descriptions for the convenience of the clinician, and there's no, what we'll call, Oracle where one can find the source of truth.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right. Let me make one other overarching comment before we go to the other discussion, and that is, we had a lot of discussion within the taskforce and with our panelists about whether you want to have truly a central repository, or whether you want to have a system of pointers that goes back to different sources in a more distributed manner. The unanimous feeling of the end users was that they want absolutely one stop shopping means one place to go, one format, one mechanism. Don't give me a pointer to another place that I have to go for something else. We tried that with HITSP. It doesn't work.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Right. Jamie, of course, first was the indirection problem, which is, if you come up with an wonderful interoperable specification that points to another place, which points to another place, which points to another place, you've lost the user. Dixie, I think your card was first up.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. I think my question is the question of clarification. Some of the meaningful use measures have to do with public health, so is this repository a superset that includes public health? I mean, we know that public health vocabularies are, in some ways, different from clinical vocabularies, the PHIN VADs, right. So is this like an über PHIN VAD that includes all the – and the other issue is with public health. The value sets may change much more frequently and quickly than they do in clinical. There are differences, and yet the vocabularies themselves are, in many cases, but not all, the same.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right. We certainly recognize that some of the vocabularies are updated almost daily, if not daily, and others change on, perhaps, an annual or even a multiyear schedule, and so there's a great deal of variation. And also, to your first question, the overriding recommendation is one place to go for all of it is really what the implementers and users demand.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes … specifically the definition of meaningful use, so anything I see in the meaningful use chart that requires controlled vocabularies would be there.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Chris, you had a comment?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I think, to answer your question concretely, yes, it does mean über PHIN VADs. The question of scope was debated somewhat. Our mandate, of course, is meaningful use. But the appetite is for any value set relevant to the healthcare enterprise touching on clinical information.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Cris?

Cris Ross – MinuteClinic – CIO
I've got three questions. This is really helpful. Question number one is, and I'm getting into sort of text parsing. In meaningful use vocabulary, is there a glossary of what's a non-meaningful use vocabulary, or are all vocabularies meaningful use? I'm not asking a facetious question.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
No. I think the scope of our discussion is constrained to meaningful use. And, in particular, we're focusing on stage one meaningful use. So what we're saying is our recommendation covers anything that is relevant to and referred to or required in stage one of meaningful use. I don't even know what else is out there that I don't know about.

Cris Ross – MinuteClinic – CIO
I think it would just be useful to have that list, not just examples, not e.g.'s, but some specific things that are in and out.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I'm sorry to interrupt … is in the IFR.

Jonathan Perlin – Hospital Corporation of America – CMO & President
It's in the IFR.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
It's the IFR list primarily, I suppose.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
If I may, I agree technically that is our scope. But I'll repeat myself. The appetite is clearly for anything, whether it be meaningful use or not, that's relevant to the healthcare process. And at least the opinion of many people is that once such an infrastructure is established for meaningful use and builds that critical mass, the incremental effort to add the rest of it, whatever it might be, is relatively modest in terms of mind share, opportunity share, infrastructure and the like.

Cris Ross – MinuteClinic – CIO
I don't necessarily have an opinion behind the question at all. I just think it would be useful for folks to understand. I mean, you've taken a lot of things to a logical conclusion, which makes a ton of sense. But if it means that every possible healthcare vocabulary of all types suddenly becomes within scope, maybe that's difficult or maybe it's not. I would think that by understanding what's in and what's out would be helpful.

My second question is exactly the same question with respect to value sets for meaningful use, as opposed to value sets …. I don't want an answer here. I don't know if anyone else does. But I'm curious if you've parsed out what are some examples of some value sets that are—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Sure. In fact, so this is, and I think we've described this that we focused initially on the value sets they required for the quality measure reporting, and so that's a good example. We have to wait for the final rule to determine exactly what the scope is for meaningful use, and then we can say more definitively what the scope is. But at this point, it would be those things that are in the IFR and the NPRM.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I can give you the classic example of what's out of scope, and that is value sets associated with physical locations around an enterprise, for example. Clearly that is not, in any reasonable way, going to be a national standard. I think one of the underpinning agendas here hopefully is as this infrastructure is established, then the mechanism and the machine were used to manage things in a federated structure, as is proposed, could scale to an enterprise level so that even local value sets or things that are not, obviously not the purview of a central repository, could be managed with the same machinery.

Cris Ross – MinuteClinic – CIO
Then the third question is, Jamie, when you and John came to us a couple of months ago and made the recommendation about how we include, for instance, dot versions of HL-7 and other things. I'm going to ask a legal question, which was, I think we got some feedback from ONC staff that there were limitations on how much that could be delegated to an outside entity, and then we needed to be strict around what standards and versions were in the regulation. I'm just asking the question, does this open up that problem again? This seems eminently practical in many respects, but I want to just understand if we run into that same legal restriction or risk of legal restriction.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes.

Jonathan Perlin – Hospital Corporation of America – CMO & President
That's interesting. In the IFR, at least the way it's currently written, it doesn't version the various vocabularies. It says SNOMED CT. It says RxNorm, etc. So presumably by providing a set of what is today's RxNorm, that would be fine—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
And if we look back, actually, I think you can infer an answer to that from the first recommendation, which is that the central authority for coordinating all these things would be a federal government office or agency, and so I think that's a part of that answer.

Cris Ross – MinuteClinic – CIO
I thought the answer before, the recommendation you made before made a lot of sense. I'm just trying to understand how this is different from a regulatory and legal perspective. As a non-lawyer, not understanding it, it would be nice to know that this was supportable under the regulatory regime, and hopefully it will be.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Right, so content standards have specific version numbers and have specific implementation guides, whereas vocabulary code sets are a database of attribute value pairs, so it's sort of fascinating. I suppose if somebody had an outdated code set, you would certify it just as you would certify against a current code set. It would just be less useful to the user.

Cris Ross – MinuteClinic – CIO
Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes. A suggestion and a question: The suggestion is that you might as well go ahead and put a comma there behind meaningful use and add Section 1561, given what's coming because there'll be a lot of code sets and value sets to fall out of that. Then the question is, when you say on your fourth bullet point there, vocabulary searchable and discoverable, do you mean at that central site they would be searchable and discoverable?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
No, well, not necessarily.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
What did you mean by that?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
What we're recommending here is establishing processes that are related to the infrastructure, but not necessarily through the central repository for parameters around the tooling that would be used for search and discovery of the vocabularies that could be used potentially locally by the EHR users. But that would be all up to this process to determine.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Wes, Walter, and Jim.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm a little hung up on this über phrase. I'm wondering which small vocabulary we're going to invade first, but the main comment I want to make is that, under HIPAA, we haven't had to have a regulatory action on ICD-9 until we went to ICD-10, even though it's versioned. HIPAA designates an entity that's a not for profit entity that has been maintaining ICD-9. And hopefully, at the level we're talking about here, we aren't asking for anything different than what the HIPAA regulations already do. Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Any comments, Jim? I would presume, again, this is the coordination function that would layer on top of those organizations, which would maintain the vocabularies, as they do now.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I'm just suggesting that the regulatory support for this doesn't require—

Jonathan Perlin – Hospital Corporation of America – CMO & President
Right.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Walter?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes. Just to follow up, I guess. It occurs to me that there might be a little bit of a confusion with respect to what is it that is required as a vocabulary, and that what regulatory specification and what are other vocabularies that are valuable for clinical practice for healthcare delivery, but that don't have a specific requirement under federal law, because I think that's part of what Cris was asking is really there is a plethora of vocabularies and value sets. But some of them have a little thing tied in there that says under regulations you must use this one. And then some of them are sort of the best practice or the standard vocabulary used in or … by someone like HL-7, but there is no specific regulatory requirement to use it. Yet, it's a very valuable vocabulary, valuable for meaningful use, as well as other things, but not required.

So it would be valuable to identify in the process, in the Web site and in the mechanism to disseminate it, which are the things that are required to be used, and which ones are available and best practice or the standards available by standards development organizations and things like that. So is that—?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right. No, and that's very much in keeping with our thinking, and I think that's part of differentiating between those things that are required and those things that are convenient and useful. And so we are recommending tight control and differentiation. Well, differentiation between those two, but also tight control over those things that are absolutely required.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Jim?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
I want to propose a slightly different dichotomy between things that are required to use HIT meaningfully and things that are paid for. And Chris' point about the appetite for enterprise needs, we need those to use HIT meaningfully. And we already are, and every other organization will do lots of things to use HIT meaningfully that doesn't get paid for directly, certainly in the early days. And so we need to remember that our goal, as a standards committee, policy committee, HHS is that meaningful use of HIT becomes an increasingly large and powerful engine, and what gets paid for at any one time, and particularly at the beginning, is only a very small subset of meaningful use of HIT. And I think our thinking and our communications with our customers and our development will all be more productive if we can keep that really straight in our heads that what gets paid for is not all of what's meaningful use.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Jamie, as a process comment, we have recommendations from the taskforce to this whole committee, and I would imagine that we would want to forward these recommendations via consensus to ONC for their consideration, and we recognize that some of these recommendations may even go beyond the scope of ONC, but given that you are the National Coordinator, you can do anything.

David Blumenthal – Department of HHS – National Coordinator for Health IT
No, I was going to remind you—

Jonathan Perlin – Hospital Corporation of America – CMO & President
Very good. I know you have one additional slide, but at least on these two recommendations, are there any further discussion or objections to adopting them with the consensus of this whole committee? Okay.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Done and so forwarded.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. There are some questions that came up about these recommendations, things we wanted to discuss with the full committee. The first question really gets to some of the discussion we just had, which is that our scope really was about the value sets that are required and the subsets that are useful for stage one of meaningful use in terms of these controlled vocabularies that are specified in the IFR or used in the things behind the NPRM. But should the scope of the recommendations also include the

base standards, the vocabularies themselves. We focused on the value sets and the subsets, not on the entire terminologies. And so we had some taskforce discussion, and a number of our members felt it would be useful to expand the scope of these recommendations to include the underlying vocabularies in full, but we wanted to have that discussion with the committee to see how folks felt about that.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thoughts on that? And, of course, the issue is that if we say that LOINC has a subset of the 98% most common ordered labs, that's 400 out of thousands of codes. If SNOMED, CORE, problem set vocabulary has 6,000 or 7,000 terms out of 22,000, so do you go to one place for the CORE subsets and another place for the entire vocabulary? How does that work?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Let me also mention that, as part of our discussion, we believe that it should be within the scope of authority of ONC to have control over the dissemination of the value sets that are required in the meaningful use IFR certification regulations. Therefore, that's something that we thought should be pretty easily. And, I mean, we may be wrong, but we thought should be pretty easily in scope for ONC to control and to coordinate, whereas getting into the dissemination of ICD, SNOMED, and as the entire vocabularies, there are other federal agencies that, in some cases, have a legal requirement that they have to follow in terms of ownership and dissemination, updating of those things. And so, in that case, it would go to more of a coordination function for meaningful use, as opposed to the direct control that ONC might have over the particular things within its own regulations.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Comments or thoughts on that? I'm seeing the general shaking of heads, suggesting that it all sounds good.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Thinking back on the last bullet of the previous slide where you called for tooling that can make vocabularies searchable and discoverable, it would seem that for that to have any value, there needs to be more than just a few starter sets. What is there to discover? It would seem to be, it would have to go beyond that.

Jonathan Perlin – Hospital Corporation of America – CMO & President
For example, in my case, that I wanted the discrete problem list, vocabulary of those terms that are the most commonly used signs and symptoms by clinicians describing a problem. And, therefore, I would want to go and discover the 6,000 or 7,000 terms in that subset. Yes, certainly it would be useful to have access to the larger entire vocabulary to look for those things that I might want to add so that I don't end up adding my own unique boutique terms.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
And in creating value sets. You're going to need a rich repository of vocabularies to create the value sets.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I've been wondering if Judy is keeping a paper bag handy in case Jodi starts to hyperventilate. With all of the—

W
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Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Right. Don't ask … IT doctors. All of the great sounding wholeness of having a single authority repository for all vocabularies, I think we ought to try to stay … bright on that issue, which is to say, for those vocabularies and value sets where there's a clear, legislative mandate, we exercise an appropriate level of control, and we find a way that, for other vocabularies, which may be developed through grant money, which may be developed by ad hoc researchers, which may come out of other industries for all we know, we find a voluntary way to make that available in a compatible mechanism without necessarily implying the governance of deciding who gets to say whether it goes on the Web site and things like that. And, as I say, we've got a lot of chance to look at these alternatives, as we go downstream.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. I think that's a good actual restatement of our recommendation because, in fact, we are recommending tight control over only those things that are required by the meaningful use regulations. Right.

M
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Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, and so, but I think, in this case, we're talking about the entire vocabularies that are in fact required, where they are required by the meaningful use regs and certification.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Jamie, all you really need is the app store for vocabularies, and we're good.

M
…right.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Any other comments on these questions? Yes, Walter.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Just a quick comment on this because similar things happened with HIPAA and the standards and the access to the standards that were named under HIPAA and the ownership of those standards, and then, of course, the money involved in it. Besides the fact that some of these vocabularies are the purview of other agencies or other entities outside of the federal government, some of them have actually monetary … attached to it, owned and distributed with fees.

And so, part of the question would become, in the first portion, the value sets, the ability for the federal agency to disseminate proprietary in the sense of owned by someone and charged for even value sets or subsets. Then if one gets to the level of the entire vocabulary, being able to actually allow that to happen without some sort of a fee involved in that when they charged for that. So a similar thing again happened with HIPAA, and now there is, of course, 5010 is actually a standard that has to be purchased rather than what happened in 4010, which was the standard was free and available. But all the other standards,

NCPDP and all the other ones, are owned and distributed through fee base access. So I would expect that we would face a similar situation with these vocabularies. And even the question of how much can subsets or value sets be available would become an issue, I suppose.

Jonathan Perlin – Hospital Corporation of America – CMO & President
And the hope would be, you would use SNOMED CT model, which is, you figure out what is the reasonable licensing fee to pay for access for the country, and it actually is rather de minimum on a per clinician basis. Luckily many of our vocabularies are free. Jamie, any other closing comments?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
The last point is really the last question here on the slide goes to some of the points that I think Chris raised very well as a summary of some of our previous discussions, and that is that we really have limited this to those things that are, according to our understanding, within the purview of ONC's authority related to the meaningful use regulations, but we did hear from many stakeholders, a desire to have much broader coordination than just those things that are required for meaningful use. In essence, we've done the best job that we think we can do right now at making recommendations that are useful and can be implemented, but we wanted to just check with the committee and see if there were other ideas of better ways to enable broader coordination other than the framework that we're recommending here.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think you have a pretty good endorsement for your framework.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay. That's it then. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Very good. Thanks so much, and I guess now onto Doug Fridsma, so we can hear more about NHIN Direct. Is Arien going to be joining us by phone?

Arien Malec – RelayHealth – VP, Product Management
I am here.

Jonathan Perlin – Hospital Corporation of America – CMO & President
You are here. Very good. The floor is yours.

Arien Malec – RelayHealth – VP, Product Management
Thank you very much for inviting me today. I apologize I couldn't be in person. I actually had my prescheduled procedure for my son, so I'm here supporting that.

I wanted to give you an update on the NHIN Direct project. I think Doug has been before you before and given you an overview about what's going on. We are about almost two months into the project, and we've actually accomplished a little bit. Hopefully we'll be on track to accomplishing a good deal more in the month to come.

There's a definitional issue for the NHIN Direct project. I think, first of all, it's worthwhile to note that NHIN Direct is a project. It is not a thing. It is not a plug or socket in the sky, and it has the word NHIN in it. That's a little aspirational more than it is a statement that the project or the specifications that we're

developing are part of NHIN as the state of interoperability framework develop, and we've got a discipline process for moving specifications through, for example, the HIT Standards Committee, through to ONC for approval. And, as we have governance mechanisms for, and we've got some existing governance mechanisms for NHIN, there is an overall process that this project is operating within. I think it's fair to say that we're early stages in that project.

The project has a goal of creating a set of policies, standards, and services, and actually our goal is to create the standards and services, and work with the HIT Policy Committee, as well as Jodi and her office at ONC and other organizations as necessary, to create a set of policies. Again, trying to be super modest, we're a project. We're creating standards and services, and our mission is to enable simple, direct, and scaleable transport over the Internet to be used for secure and meaningful exchanges between known participants in support of meaningful use. There are a large number of health information exchange needs and we're not solving all of them. We're trying to focus on what's been identified as a business need, as a focused problem in healthcare, where the addition of standard mechanism would help.

There have been a lot of questions about where and how does the NHIN Direct project fit with the overall NHIN, and the way that I've described this in the past is to look at a clinician's perspective. And note that there are a number of services, many of which are expressed in the NHIN, to solve the problem of a patient presents, where else, across systems, across national HIOs, has that patient been seen, and what information is available about the patient. And so, at the beginning of an encounter, a clinician may want to know that question. Where else has the patient been seen? What information is available about the patient, and then retrieve the information to support continuity of care.

At the end of the encounter, the clinician may want to update their own HIO, either could be a large IDN information system. It could be a state HIO. There are a bunch of ways that they could end up doing that. Then at the end of the encounter, they may need to refer the patients over for care, and so a lot of the current mechanisms for the NHIN are information access, information retrieval. But when you refer, you're referring to a provider. You may be referring to, for example, the cardiologist. And you've got an expectation that that information transfer to that provider. And you've also got an expectation that that's a direct transfer.

Another interesting use case is a discharge summary at the conclusion of an acute hospitalization. You may want to publish that discharge summary to a big repository in the sky for other people to have access to, and the current NHIN specifications address that case really well. But you also want to get that discharge summary to the primary care provider, to the referring provider, and you want to get that directly. You don't want to get it indirectly because, generally, the provider is going to pull that record when the patient is seen in the practice. One of the points of a discharge summary is to get it to the provider immediately.

There are a bunch of cases where the notion of a directed push transaction that ends up getting routed to an individual or to a generic endpoint ends up being a useful mode of health information exchange. What you see here is, on the bottom, there's a couple of design … with the slide that I'll talk to, but it gets the point across, I think, pretty simply. If you look at the bottom, you've got the current set of services that are available on NHIN, and a couple of things.

First of all, those services that are currently operated on the NHIN exchange are node-to-node services. They're targeted messages, which means that if you do exchange, you need to know the other HIO that you're doing the exchange with. And that's an incredibly useful mode of operation. If you're getting transitions of care, oftentimes you may know where that patient has been seen before, and so you may

want to search their information in a national HIO. You may have a set of national HIOs that you may want to query against, and you may individually decide to query against a bunch to get the maximum information possible. But by design, these transactions require you to know where you're getting the data from.

The second thing to note on the bottom is that also by design, the edge specifications, how an individual clinician hooks into the node is left undefined. Again, that is by design. And so there is, for example, a submit documents transaction that is a pushed transaction that's available on NHIN today. But it works extraordinarily well if your goal is push a document or set of documents from, for example, CMS to or from an IDN to CMS to support some continuity of care, to support a claim, or to support any of the information where you might need that push.

What it doesn't do is solve this use case of get information all the way out to the addressed recipient. So what you see at the top is the model of exchange for what we're trying to solve in the NHIN Direct project, and this notion, instead of being node-to-node, is endpoint-to-endpoint. It is a routed exchange, so you don't need to know, by design, you don't need to know who serves exchange for the endpoint that you're trying to address. You just need to know who that endpoint is and what their address is. And the edge specification, how an individual EHR, for example, plugs into the exchange are explicitly part of the design space that we're trying to explore. So there's one leg of this, which is, route patient information where you do have a directed transaction potentially between two nodes or two HISPs, as we're calling them in the project. But that's kind of the only point of overlap between the current NHIN exchange model and the NHIN Direct project exchange model.

The other thing, I think, that's worth noting is that there's going to be a transition in this country between providers who have simple exchange capabilities moving towards more robust exchange capabilities. And so we believe in ONC and in this project that there'll be a transition from clinicians using simple modes of transport like the ones that we're providing in the NHIN Direct project, to continuity of care that ties back to meaningful use. We believe that some of the transactions that may need to be supported up front may end up getting replaced by more robust HIE transactions. A good example of that is that in a transition of care, I need to provide a care summary document, and I need to be able to provide that in a CCR or CCD format with specified information.

If I know that the receiver of the referral, for example, has access to robust exchange capabilities that are plugged into NHIN, I have some confidence that they can pull down the clinical summary from their exchange. If they don't have access to that robust capability, I may actually just want to publish and attach that CCD along with the referral that I'm sending over to make sure that the refer to provider has continuity of care. And so we believe there's always going to be a need for routed, directed messages. We believe there's a clinical use case for routed direct messages. But we also believe that some of the initial use cases for the kinds of transport that we're talking about will end up getting replaced over time by more robust exchange capabilities.

M
We're on the project member list.

Arien Malec – RelayHealth – VP, Product Management
Okay. So my slides aren't keeping up to date with those slides. The list of members that we have engaged in the project is rich and diverse. We've been, I think, extraordinarily fortunate to get a good deal of membership. You'll see on this list a number of, for example, the leading PHR vendors, the leading EHR vendors, the leading HIE technology vendors, but it's not just the technology stakeholders that are involved in this project. We've got stakeholders who represent, for example, state HIEs, local

RHIOs, RECs involved in the process, as well as some large, national organizations that provide nationwide exchange capabilities or nationwide information access capabilities, as well as a number of associations that represent the interest of EHR module providers, as well as smaller physician practices themselves.

There's a selection bias problem in standards development where the organizations that can most participate often represent the interests of more often our larger organizations. There's nothing wrong with that. We just also need to make sure that we have access to and represent the interests of smaller providers in this process as well.

We can go to the next and, Doug, if you can remind me what it is while I get the—

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
This is about your members. I'll track pretty closely with you. You just talk.

Arien Malec – RelayHealth – VP, Product Management
Okay. I'm going to see if I can get back into the presentation so I can see what we're tracking again.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
This is your community implementation groups and the various working groups that you've constructed.

Arien Malec – RelayHealth – VP, Product Management
Excellent. Thank you very much. This is kind of like doing presentations in the dark. What we've established as part of the overall project, we've got a large group of implementation group participants. We've broken that work down into a set of focused implementation working groups or a set of focus working groups that are taking parts of the overall elephant, if you will, and working them bit by bit. And we've gotten a lot of good, both community involvement as well as implementation group involvement in this process.

One of the hallmarks of the project that we're trying to make sure that we adhere to is use of this as an open government process, so we do have a number of members in the implementation group that have committed to doing real world implementations, but there's also a good amount of community involvement and organizations that are getting involved and actually just contributing to the project. We've got a mixture of both formal working group participants, as well as the larger community effort who is participating in the process.

I won't go into the details about what each of these workgroups is doing. My computer seems to have decided that now would be a really good time to just go take a nice lie down. Let's see if we can get back. Doug, can you go to the next slide and remind me what it is?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Do you want me to talk through this next slide while you—?

Arien Malec – RelayHealth – VP, Product Management
That'd be great while I get back into the activity.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Sure. I'm just going to talk very briefly about the members. I think Arien has done a tremendous job in actually organizing this widely diverse group of folks into very focused working groups that are actually moving forward in delivering real input into the process, which I think has been tremendous.

As Arien was saying, the NHIN Direct project is open and collaborative in the sense that there is this implementation group that is focused on delivering the real world implementations and the specifications, and have committed real resources. The working groups are really open to just about anybody who wants to participate. In fact, there is, as Arien said, a broad range of folks that are engaged, companies from the size of Microsoft, to smaller medical nonprofits like Cautious Patient.

I think we are cognizant that there is potentially a bias in the groups in the sense that there are a lot of larger organizations represented, and I think it's going to be important for this group to keep us honest, to make sure that we are representing and following the principles of the implementation workgroup, that we're thinking about the little guy, and that we're doing the right thing. I think one of the ways that helps with that is that we're trying to do this out in the open, and so the NHIN Direct wiki is open to everyone. We've got 180 members who are actively engaged in dialog. We've been very, very fortunate to engage Brian Behlendorf, who was one of the thought leaders with regard to the Apache open source project who is providing us guidance about how to manage communities and how to get these large, open source communities to sort of direct their energies and get to the point of engagement.

All of our implementation groups and work calls are open to all. I've had to get new call in numbers because we were exceeding the capacities of the teleconferences that we had arranged. And all of the discussions are archived and searchable on the wikis and through the threads and notes that are published after each call. So we've really tried to take the open government initiative, apply it to this particular project, and use that as a model for how we are doing the work of this particular project.

Arien, I'm now on the NHIN Direct with the graphics. And obviously this is not a group that works on the weekends because there's these dips, I think, in the NHIN Direct views and things like that. But you can see that we've had a lot of activity in terms of people that are coming to NHIN Direct, the Web site, and taking a look. There's, on average, it looks to me like the days have been running with a peak around 2,000 unique hits, and so there's a lot of good activity there. And then you can also see that it's not just people looking, but there are people who are actually editing, and you can see that even though there are ups and downs in the edits that are seen there, that the trend is actually increasing in the sense that we have more people who are participating, editing, and actually adding comments to the area.

Arien Malec – RelayHealth – VP, Product Management
Yes. We also have a lot more content. It's getting to where actually gardening the wiki is going to be a key activity to make sure that all this information is searchable. I think I'm back. Are we on deliverables and timelines?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
We are.

Arien Malec – RelayHealth – VP, Product Management
Great.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
We're actually separated at birth, Arien and I, so we can do this twin talk stuff.

Arien Malec – RelayHealth – VP, Product Management
It's so much fun. There's a Murphy's Law with respect to information technology that it will always go out just at the moment that you least hope it to, but it works perfectly in other times.

The timeline that we have is an extraordinarily aggressive timeline, and the reason for that is that the meaningful use timeline itself is also an extraordinarily aggressive timeline. And we believed that, as one of the organizing biases of the project, that specifications are best developed in the presence of implementation, in the presence of working tested software, and that putting a set of constraints around getting up and running was one of the best ways to make sure that we were modest and focused in our scope, that we aimed for the right amount of simplicity, the Eisenstein quote of as simple as possible, but no simpler. And so we're organized around putting together real world implementations involving real world providers in September/October of this year, and we believe that if we can achieve that, we're in a good place to widen that activity and ensure that we can provide at least the basics for information exchange for the wider set of providers for the meaningful use timeframe in particular towards mid 2011.

If you look at what we're trying to deliver, we've got an overall set of delivery objectives out of the project, and the next slide will explain that, and we've broken that down into a set of milestones where the first milestone, we have a face-to-face meeting next week in D.C. The first milestone is organized around making some of the high level, the set of high level constrained choices. We've got an organization or a working group that's right now exploring some technology options and will be giving us recommendations.

We've had working groups that have been exploring security and trust models, that have been exploring how to package health information for exchange, and those kinds of things. And those working groups will come back and give us direction that helps us constrain some of the technology choices we'll be exploring. By the beginning to mid June, we'd like to have the final set of specifications that we're aiming for, and we will report back to the standards committee towards the end of June with what that final list is, and that will be the language lawyer kinds of standards that people can build software off of.

Now my bias, and it's actually part of the recommendations of the implementation workgroup of the standards committee is that you need to give more than just the specification documents to technology enablers, and so we're also focused around providing a set of testing harnesses, testing tools, and implementation guides that are designed to make it easy to take the specification off the shelf and know how to hook into it, as well as open source reference implementation so that if you're on a similar technology stack, you can actually just plug in the reference implementation. And if you're on a different technology stack, you can look to that reference implementation to give you ideas for how to enable interoperability. Those timeframes are organized around mid to end of July. And so all of this is, as I said, leading towards that September/October date where we hope to have real world implementations, and we will come back to the standards committee and give you updates on where we are with the actual specifications that we've developed in the project.

This one is the final deliverable. Part of what we're doing in this project is basically serving as a model for, and by model, I mean both a good model and a negative model where we're going to learn a ton doing this work, for how to shepard new standards or new proposed standards through a disciplined process that has all the right objectives that Doug has been looking for in the process work that he's doing at ONC. And so one of the key deliverables that we want is a set of formalized models for the services, for the specifications, both content models to the extent that we're doing content, although most of what we're doing is content packaging, as well as service models.

One of the benefits of a model driven approach is that we can then start to automate the development of some of the testing apparatus and testing tools and have better specificity for knowing when we're doing. Of course, we have to have the core specifications and service descriptions. That, as I mentioned, is the language lawyer kind of stuff that tells developers where the bits and bytes go. And two additional things, as I mentioned, need to go along with that: the conformance testing scripts and service, as well as the set

of documentations around for implementers that help them get up and running. And we've already gone over those.

In addition, we'd like to make some process recommendations for how this project worked. Was it a success? Was it a failure? What worked? What didn't? What are lessons that we can learn out of this process for informing the way that, as I said, new standards or specifications go through the system, as well as there's a technology policy overlap. We're trying to be very cautious of making sure that policy is driving technology and not the other way around. But we're also very cognizant that you discover policy issues when you implement technology, and so we've got an open channel to the NHIN working group or workgroup of the HIT Policy Committee, as well as an open channel into the policy organization of ONC to make sure that we're surfacing all of the key policy issues that are related to technology.

Then, finally, standards and specifications are part technology and part awareness, and so we do have a goal of making sure that we have strong awareness of what it is that we're doing and what it's good for and what it's not good for so that we can help the country move forward to robust interoperability in 2011 and beyond, and so there'll be a whole set of activities that we'll take on there. Now those activities, of course, are contingent on us being successful with the project, so the first thing is first, I guess is what I'd say there.

So we've got this face-to-face meeting next week, and you can see on this list, some of the key deliverables that we've got up and running. We've got a finalized set of user stories that we're driving to, ways of packaging content, ways of enforcing a security and trust model that conforms to the policy direction that we've been given. The statement and statements about how these services will interoperate with the current set of NHIN services, as well as the set of robust HIO services that many of the states are putting together, so we've got a good model for how all of these services fit together and work together at scale.

How we involve the individual, that is the patient, you and me, how we do addressing, how we do abstracting, and what the abstract model looks like, and then we've got an implementation group right now that's up and running or a concrete implementation group that's exploring some of the technology options, and we expect them to come back for May 6th. That is a brief description of the project and where we are. I'm going to stop now and open it up for questions. Thank you very much.

John Halamka – Harvard Medical School – Chief Information Officer
…a number of us on the standards committee are on the implementation workgroup, and so I volunteered my 1,700 clinicians, some of which are big, and most of which are small. The average size of a practice in Massachusetts is 2.5 docs, and to say that we're going to actually try to send some transactions using the NHIN Direct addressing and transport protocols to communicate some continuity of care information not only among this group, but also with some other states. And this is a project. We don't know if it's going to work, but we'll certainly learn a lot along the way.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Your card went up first, Carol.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I have to go back to almost the first slide that you presented because you lost me a little bit there. And maybe this is a little bit of a Rip Van Winkle moment for me, but I remember this NHIN Direct work kind of starting with the send, if you will, piece of the model. And I heard you talk about the sort of sending or sending with services. But I also heard you open up with, this is about finding where a patient's information is and what kind of information is available. Are you also doing find?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
No. Thank you very much for that. No, I was doing a compare and contrast, and trying to help situate the narrow problem that we're trying to solve, which as you say is the push transaction between known participants and trying to, and obviously not going a very good job of it, to situate that narrow focus in with the wider capabilities that are offered currently on NHIN, which do encompass the query and pull model.

Arien Malec – RelayHealth – VP, Product Management
To clarify, the black arrows are NHIN Connect. The green arrow is NHIN Direct, so it's—

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
My clarification slide didn't really hit the mark, so I apologize for that.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. The color-coding wasn't intuitive, let's just say. My second question is actually related to policy. I made an earlier comment to this effect, and I'm going to make it here again. I know I'm on the NHIN workgroup, and we haven't really provided much policy direction to you other than saying there needs to be a trust framework in talking about the elements.

I'm wondering what kind of policy input you need right now since it sounds like you're very far along in some of these specs. And I'm also wondering if you have a security and trust workgroup, I guess, that's actually writing a spec. And I know that there's a policy committee, privacy and security group. We have a privacy and security group here in the standards committee. And I'm just wondering if we've thought through the coordination or at least the appropriate inputs to all of that. I guess, at the end of the day, my question is, how can we do a better job of that because it's certainly not apparent to me?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Thank you for that. I've put together a set of policy framing issues that come out of the work that we're doing, and I guess on of the things that I suggest is that potentially we use the next NHIN workgroup meeting to walk through some of that. We could definitely be doing a better job of making sure that we're coordinating the policy input and making sure that we're kind of running as fast as we can in the project, and I'm trying to surface up the key policy issues, and so we'll do a better job and welcome and open to working with both the full policy committee, as well as the subcommittee of the policy committee and the standards committee in areas where it makes sense.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. I just want to punctuate, I know everybody is anxious to give you what you need in the timeframe that you need it. But if we're down to the level of really writing specs about some of these things, many of those determinations and standards will in fact bring with them policies. So we might as well get to it now.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Agreed.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Rather than later. Then finally, can you just, on the bottom of this same slide, it says PKI. Can you just talk a little bit about that?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

There's an existing PKI model that exists for NHIN, and so that bottom of the slide is really referring to the existing PK apparatus for the NHIN exchange itself. We are looking at a PKI infrastructure for trust enablement, for the NHIN Direct services. And, as I said, we'll find the right places to make sure that we're getting the right level of policy input there.

John Halamka – Harvard Medical School – Chief Information Officer
Doug, again, pardon me, NHIN Connect infrastructure. Using the set of existing NHIN structures, whereas the NHIN Direct is a very thin model with very simple push transactions in a very simple directory. Yes, I think you're right. The slide probably needs to be cut differently, a dotted line across the middle or something like that.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Yes.

John Halamka – Harvard Medical School – Chief Information Officer
David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes. It's David McCallie, and I'll steal from Stephen Colbert. I have a tip of the hat and a wag of the finger for you Arien. The tip of the hat first, which is, as someone who's participating actively in the NHIN Direct process, I think Arien and Brian, who is helping him, and a lot of other people deserve a lot of recognition for the incredible amount of hard work. The number of meetings per week that Arien attends, documents, summarizes, and manages is astonishing, so I think you're doing a terrific job.

The wag of the finger is I want to just slightly pick a bone with you about the words you use when you introduce your first slide, and you contrasted NHIN Direct with "more robust alternatives." And, I for one, I think that what we're trying to build with NHIN Direct is a very robust, direct messaging protocol and set of services. There may well be more complex services, which replace it in the future, but it's not due to lack of robustness in the definition of what I mean by robustness, which involves the standard issues around security and integrity of data exchange and so forth. Just to pick a bone with you, I don't think we should contrast NHIN Direct to "more robust services." I think it will be a robust, direct messaging service, which may or may not be replaced by more complex services in the future. Does that make sense to you?

Arien Malec – RelayHealth – VP, Product Management
I agree with that. One thing that I'd also like to make sure is that we're not talking about an alternative. We're talking about complements, again, in just following the fact that the use cases are different, and so the transactions are different.

I've been trying to find a good way of making the distinction between simple directed transport that is robust from a security perspective, completely agree with that. But has an overall, simpler orchestration from both the technology and from a policy side with the kinds of information access capabilities that are provided on the current NHIN and so I'm open to finding the right set of words to make the compare and contrast appropriate.

I think the wider point that I want to make is that, A, both these services are going to be available and needed over time and, B, different use cases want to do different kinds of things. Then, C, some things that we'll end up doing in simple ways will end up migrating towards the more sophisticated, maybe is a better word, information access patterns.

John Halamka – Harvard Medical School – Chief Information Officer

And so what I would postulate is the word comprehensive is really what he's after as opposed to robust in the sense that today when you look at NHIN Connect, it's got push. It's got pull. It's got discovery. It's got patient matching and ID. Whereas the use case that he's trying to solve with NHIN Direct is a very simple, thin push. But in fact, as he said, they're very complementary, and the intent is that one could connect with the other.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
But I agree. I think we run the risk, however, of confusing implementation with capability. So the capability for universal, addressable, secure, side effect free, direct messaging must exist regardless of the underlying technology. That technology today and in the next several months, may emerge on top of this project. But that capability, secure, universal addressing, etc. with direct messaging, side effect free, will not go away, even if the technology suite underneath it completely changes.

NHIN Direct, in my view, is about both of them. But the real value add in the long run is the recognition of the value of universal addressing, any provider, any patient, anywhere, anytime, secure delivery without side effect. And the protocols may change over time, as we get more sophisticated about how we do that.

John Halamka – Harvard Medical School – Chief Information Officer
Well said. Kevin?

Kevin Hutchinson – Prematics, Inc. – CEO
First of all, I want to give kudos because this is probably the first time that the lights have now gone off for me about the differences between NHIN Direct and the NHIN now with the NHIN exchange and Direct, so I may be slow, but now I understand it a lot more than I did previously.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I think it was the colors.

Kevin Hutchinson – Prematics, Inc. – CEO
It was the colors. And I like the dotted line idea. Very good. Yes, green is good, but I have one question. It's centered around this, in the green, it talks about patient information, and I want to distinguish something because we talked about the exchange of patient information, and we talk about the continuity of care record and referrals and things like that where patient information is being exchanged. But in the concept of NHIN Direct versus the NHIN exchange, is there a separation between content and B2B type transactions? A radiology order, a lab order, a medication order, something that is an actual, almost like in the finance world, would be more of a B2B type transaction versus an actual sharing of patient information and content. Or are we putting all of those types of transactions under the umbrella of patient information?

Arien Malec – RelayHealth – VP, Product Management
More the latter, and the current set of NHIN specifications and the specifications that we're working towards in this project are content neutral. That is, we're looking at solving the problem that I think David really well articulated, which is universal messaging and routing and addressing. How do I get information to provider X or to the lab or to the hospital or to what have you? We're trying to separate that problem from, and then what does the package contain?

I want to acknowledge that when we do that, that they're both incredibly critical questions. But definitely the intent is to support things like an order transaction, things that contain PHI, contain clinical data that are more administrative in nature.

John Halamka – Harvard Medical School – Chief Information Officer
One way just to think about this is that today I have a secure e-mail among many of the Harvard associated organizations. But to be honest, when a provider sends and e-mail from my e-mail system to an external e-mail system, they're not really sure if the endpoint on the other side is secure. And so, for example, what if NHIN Direct could say, one mechanism, and I'll use David's favorite example here, is simple e-mail transport with security and, in fact, I now get to operate nhin.bidmc.org. Therefore, we all know that an NHIN talks to an NHIN node, and anything that goes, whether it's patient ID information, a referral, e-prescriptions, whatever, it's going to be completely secure and robust. That's the idea. It's really content neutral. The package could be any of the standards we've talked about here. Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. This morning, as I said, I'm taking my words back. I mentioned that everything is coordinated, and I have to tell you that on both of these security and privacy workgroups, on both the policy side and the standards side and I've never heard of any of this, so thank you, Carol. In fact, our last security and privacy policy workgroup meeting, it was all around discussing what is an NHIN point-to-point exchange, and we haven't had that conversation with anybody on this project.

There absolutely is a lot of policy around this. We were talking about things like how private information could get in the header. We talk about things like could that router be a clearinghouse. So we're talking about a lot of issues in that workgroup that absolutely need to be better tied with this project, and call me selfish if you will, but I don't think I should be the one to have to reach out. I would think the project would be wanting to talk to both of those groups, but beginning with the policy side, quite frankly.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
And I would agree with that, and I apologize for the oversight, and so we'll take that as a clear action to do much better on.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
…point about the conversation to the privacy and security workgroup on the point-to-point exchange. That was, I mean, Arien wasn't invited to those discussions, but that was basically in direct response to questions that were coming up from the NHIN Direct folks on privacy and security issues, as they related to NHIN Direct. That's what started those conversations, and the hope was that some of the recommendations coming out of the privacy and security workgroup and through the policy committee would help inform NHIN Direct work. So we can, obviously, make that more closely aligned and maybe even bring Arien to those discussions.

But the intent of those discussions were when folks were talking about kind of more robust exchange and privacy and security policies. We had talked with Deven and Rachel, the two cochairs, about kind of bringing that back to this more point-to-point exchange, and having a discussion there first to help inform the work of the NHIN Direct. So any suggestions on how we can do a better job of that would be appreciated, but I think that was what we were starting to do and why we brought that conversation back to the point-to-point exchange and the privacy and security issues related to that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The only suggestion I would have is that the timelines are out of whack because this is farther long, way farther along, it sounds like it, than the discussions we're currently having in the workgroup.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Although it matches what Deven ….

John Halamka – Harvard Medical School – Chief Information Officer
You're next, Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
First, a question for Doug. Let's suppose that this project is successful, and we have some participants in the project who decide to exchange data based on the specifications that were developed. Is there any federal regulation or law that prevents them from doing that?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Whenever you talk regulations, I always look over to Jodi.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes. Let me be specific. Are there and standards produced by ONC or are you aware of anything other than HIPAA, which regulates how two independent providers decide to exchange data?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Not to my knowledge.

John Halamka – Harvard Medical School – Chief Information Officer
I'll give you the very, very simplistic answer, and then Jodi can give you the correct one, which is the conversation that I had with Arien at noon today was, what we were trying to simply do was replace an existing fax machine transaction, and you follow the exact same workflow that you use between two fax machines across the state border. In effect, that's what we would be doing here. Sure, there are many, many laws, and there's consent, and all kinds of complex issues. All we're doing is changing a fax machine into a ….

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
This is really preliminary to the big question, which is what is the status of this specification at the completion of the project? Is it a standard? Is it a group of people that got together and did something? What is it?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I think that's an excellent question, and in fact it's one of the things that we talked a little bit about this morning when we were talking about the standards and interoperability framework. NHIN Direct is a project that's developing specifications. We can assume, or at least we can hope that there will be other kinds of projects and other kinds of specifications that may come down the pipe that say we have an idea about how to exchange information that we think is a valuable way to do that.

Some of those groups may come to us and say, we want this to be part of the broader nationwide health information network. We want this to be part of that toolkit. And we want there to be a process by which we can take the things that we worked on and have them become a part of that toolkit that we've got.

Arien sort of alluded to that as he was talking about sort of process and feedback and what our deliverables are. And I think, at the end of the day, we may have a specifications that may have raised policy issues around privacy and security that we haven't quite resolved yet. There may be other things that might come down the pipe that would say we need to, in addition to the NHIN Direct project, there are other things we need to work on.

So one of the things that I'm hopeful that we can, in parallel, as NHIN Direct is sort of finalizing their work, is try to understand what happens at the end with these specifications. Do they automatically become part of our toolkit? Is there a criteria that we use that sort of say, if you meet these criteria, and you have some sort of process by which they get incorporated, we can then give it our stamp of approval.

We don't have those processes in place just yet, but we need to get those in place in anticipation of this because I want to make sure that whatever we do is open, transparent, and understandable so that if the next person coming down the pike says, well, why didn't my stuff get in? We have an explanation as to why our policies and our principles, and what is guiding us in terms of incorporating that into our toolkit. You raise a really important point, and it's on our radar, and it's part of the discussion that we had this morning as well.

John Halamka – Harvard Medical School – Chief Information Officer
Go ahead, Jodi.

Jodi Daniel – ONC – Director Office of Policy & Research
The one thing I would say also is that, and I don't know every law and regulation that's out there to answer your question specifically. HIPAA obviously is there. Our standards regs is a vehicle for adopting standards and implementation specifications. We also have authority under HITECH or a requirement under HITECH to develop a governance mechanism for the NHIN. I expect some of the discussion in this might inform some of our thinking on NHIN governance, which the NHIN workgroup of the health IT policy committee will be talking more about and hopefully making some recommendations on, and we haven't scoped that out in detail. So I'm not sure the level of detail we will put forward in regulation about NHIN governance, but that's another area where some of the work coming out of NHIN Direct might help influence policy in that space as well.

John Halamka – Harvard Medical School – Chief Information Officer
Sorry for leading the witness here, but trying to get to a point, which is that as far as I know, there is nothing in any regulation that's been issued pursuant to HITECH that would compel anybody to use this stuff done in a specification. It might happen. It might go through a regulatory process and do it, but if no one is compelled to do it, and no one is compelled to get certified to do it or anything like that, just on the basis of this project.

Furthermore, if they happen to want to use it voluntarily, this project is based on the notion that the determination process for consent whether the person I'm sending it to is actually who they say they are and so forth, is parallel to that that's done with the fax machine today. So I am glad to see the offer of support on policy and standards. I certainly hope that the statements like, well, this schedule is way too aggressive because we can't possibly give the support on policy and standards in that timeframe, boil down to we understand when we need the guidance appropriate to the regulatory process as opposed to when we need the guidance in order to meet the current timelines of this project.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We are running … schedule. We want to give the DEA folks a chance to do their presentation, but we had Wes jumping out of his seat. Dixie, Kevin, and David, one or two sentences, and then we'll just wrap up.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. If this is a fax machine, is this NHIN Direct an exchange between a provider and a clearinghouse or a provider and a provider by way of the clearinghouse.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
A provider and provider by way of a clearinghouse, I think, is the best way to describe it.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
There's no clearinghouse.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
He said there was. There could be.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Right. Clearinghouse is a bad terminology, but there's an assumption that there's an HIO or a lightweight health information service provider who is in the mix as opposed to thinking of this as bits that go directly from one provider to the other provider. There are some policy implications around that in terms of what's the role of the health information service provider in the transaction.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay. Thank you.

Arien Malec – RelayHealth – VP, Product Management
I've been waiting for eight years for the next presentation, so I'm all ready to go for the DEA.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes. Just to point out that there are dozens, at least, of private, proprietary, secure messaging systems in use today by providers. SureScripts has one. Emdeon has one, AvaMedics, the vendors have one. What is different about this is that it would be universal, and it would be something that we've all collaborated on, all of the people that run proprietary systems today collaborate on so that that universality is accepted. Otherwise, I don't think it changes the picture very much from a regulatory point of view compared to what already happens today, and if you through the fax machine in.

Then, Dixie, with respect to the clearinghouse, I think the analog is, in NHIN Direct, there's something that plays the role of the central telephone exchange that routes your fax to the other guy's fax. But that's all it does it is just makes the connection. It doesn't store anything.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Reads the header at the very least.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
It reads the routing headers, yes. And we've purposefully made those minimal.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
So it really isn't a fax machine. It's really a routing—

David McCallie – Cerner Corporation – Vice President of Medical Informatics
There's traffic analysis is possible on the fax machine from the central exchange's point of view. You can see which phone number sent to which phone number, so this is the same as that, no better, no worse.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great. A really great discussion. I had no idea we'd have so much fun after lunch. Arien, just so you know, everybody is smiling here, so hats off to you, you've had a few recommendations, and we look forward to the next step.

Arien Malec – RelayHealth – VP, Product Management
Thank you very much.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Just before John introduces the next subject, obviously if there is more ground to plow on this topic, so obviously it's coming back, and the other is the theme of making overt, structured, and synchronized privacy and security activities is definitely on our to do. Just to close those …. John, back to you to introduce the next topic. I don't want to make Kevin wait more.

John Halamka – Harvard Medical School – Chief Information Officer
We have waited, of course, with great anticipation for the discussion from our friends from the DEA about unifying all e-prescribing processes. Now do we have – is Michelle here. Very good. The floor is yours, and certainly our hat is off to you for solving what has been a problem that has long needed a solution. I, as a clinician, look forward to being one of the earliest adopters.

Jonathan Perlin – Hospital Corporation of America – CMO & President
For those on the Web cast, we're going to start with Jodi Daniel from the Office of the National Coordinator, and Michelle Ferritto is Chief Regulatory Drafting Unit Office of Diversion Control of DEA is here to co-present these activities. We'll go to Jodi Daniels first.

Jodi Daniel – ONC – Director Office of Policy & Research
Thank you very much. Kevin, this is for you. It's great to be able to talk about the e-prescribing controlled substances, and I'm just going to basically talk about how this connects with HHS's health IT efforts and our work with DEA and then Michelle will get into the details about the regulations, so I just have a couple of slides.

We have been interested in this issue for some period of time, particularly because we wanted to make sure that all providers who want to e-prescribe can e-prescribe, and the ban or the inability to e-prescribe controlled substances was something that we wanted to address because we heard from lots of different folks, not just Kevin, about how this was a real challenge for folks who were interested in e-prescribing and were interested in broader use of health information technology.

From ONC's perspective, we were concerned about allowing this, but in a way that worked for provider workflow so that it was something that not only was possible and legal, but also something that was practical for providers to do. We wanted to make sure that the benefits of e-prescribing reached all patients, including patients that received prescriptions for controlled substances. What was very important was trying to promote the harmonization of DEA's regulation with HHS's rules on implementing provisions of the HITECH Act. With that, we had a very collaborative effort with DEA, and I really want to thank DEA for working so closely with us, as they were developing the regulation, so we could develop an approach that met both agencies' missions. Obviously DEA's to prevent drug diversion, and ours to try to promote improvements in the quality of healthcare.

We became involved after DEA published its NPRM, and it was ONC, CMS, and HRQ that had worked closely with DEA in analyzing comments, discussing potential options, and working with them, as they were developing their final rule. So I really want to thank publicly the DEA for their collaborative work with us. I think it really led to a rule that we feel we can support, and we think is a very good rule for this space.

As far as the connection with HHS's activities, we thought that this was a very important regulation to allow full adoption in meaningful use of certified, electronic, health records. We know that there are people who were not able to adopt because they were high prescribers of controlled substances, or even folks that were not necessarily high prescribers of controlled substances who didn't want to have two different processes in place, so they were reluctant to switch to e-prescribing if they did do some prescribing of controlled substances.

We had heard from a lot of different people about the importance of this toward adoption. Through the State Alliance for E-Health, we had states promoting e-prescribing within their states, and this kept coming up as an issue in that context. We heard a lot from the Hill about this. Probably DEA heard more from the Hill than we did, then also obviously providers that were interested.

One of the things about the timing of this that I think is really important is that the DEA regulations have come out at the same time as we are working through our regulations and put out our interim final rule on our initial set of standards and certification criteria. And I think this is really great because it allows, as folks are upgrading systems to meet requirements that HHS is putting out for standards and certification criteria, folks can look at the DEA regs at the same time and do upgrades at the same time.

The one thing I would note is that the security requirements and the DEA regs, and Michelle will go through these in much more detail; do go further than HHS's health information security requirements through HIPAA or through our standards rule. And we think these still work well together, and we actually hope to learn more about how these security policies are implemented and how they work in practice within this context, but how that might translate in a broader context for EHRs and for e-prescribing more generally. So I wanted to start off this conversation just to let folks know that this really was a collaborative effort, that we really appreciate the hard work of DEA. We think this is a great rule. We think the timing is perfect with our regulatory efforts, and that we look forward to continuing to work with DEA, as they get comments back on this regulation. And we'd look forward to any input folks have on the intersection of our regulations and the DEA rules. With that, I'll turn it over to Michelle.

Michelle Ferritto – DEA – Acting Administrator

Thank you very much, both for inviting DEA to speak about this rule, and thank you, Jodi, for your kind words about the rule and for your support throughout this process. We very much have appreciated working with all of the components within HHS on this rule. We believe that we really have developed a very good working relationship, and we look forward to continuing to work with you in this collaborative nature, and to implement this rule in a successful manner. We appreciate that, and we appreciate the opportunity to speak here today.

Moving to the slide on electronic prescriptions for controlled substances, as Jodi noted, the rule was published on March 31st. It's an interim rule. It becomes effective June 1, 2010, and that's the same day that the comment period closes. So we certainly look forward to that implementation date.

We worked hard over these last several weeks to make sure that the word is getting out to everyone about the publication of this rule. We provided to you a number of question and answer documents that are available on DEA's Office of Diversion Control Web site. We've specifically designed question and answer documents for prescribing practitioners for pharmacies and for application providers about this rule to try to break down what is a rather lengthy document into something that's easy to use and simplifies it for each one of those groups that are involved.

Moving to the overview slide, just a general discussion of the rule, and we'll get into each of these points as we move through the presentation. The rule provides practitioners with the opportunity and the ability

to sign and transmit prescriptions for controlled substances. This includes controlled substances in Schedules II, III, IV, and V, so all controlled substances, which have legitimate medical uses in general practice are addressed by this rule. And it allows pharmacies the ability to dispense the prescriptions that they received based on those electronic prescriptions. It's important to realize that while DEA's regulations address all controlled substances for which there are legitimate medical uses, I do want to note that these regulations are also related to any state laws or regulations that may be out there, so if a state has laws or regulations that are more stringent than these, those state regulations or laws would need to be complied with.

Looking at what this rule also considers, it does not address written prescriptions or oral prescriptions, so those remain untouched. It is still legally permissible from DEA's perspective for a practitioner to write and manually sign a prescription for a controlled substance. It's legally permissible to transmit an oral prescription where those prescriptions are already permissible. I also want to make clear that it's permissible for someone to use an EHR or an electronic prescription application to create a prescription, but then decide not to sign and transmit it electronically. But rather, to use the rest of that EHR technology to incorporate that prescription into the electronic health record or other records, but to print that prescription off of that EHR application, manually sign it, hand it to the patient, and allow the patient to take it to the pharmacy.

This rule is voluntary from DEA's perspective. We recognize that HHS certainly has concerns and a stake in the adoption of this rule as it relates to other e-prescribing efforts, and we certainly look forward to working on those, but we want to make it clear that EHR and e-prescribing applications can be used to get this data into other parts of electronic health records without actually signing and transmitting the prescriptions electronically if that's what the practitioner wants to do.

Moving to the next slide on our cooperation with HHS and with other agencies, we've already touched on this, but just to reiterate it. We really do appreciate the work that we've undertaken with all the different components within HHS. And DEA also worked closely with NIST and with GSA on this rule, and we appreciate their efforts as well.

Looking at the implementation of this rule on the next slide, and who the rule affects, and who it addresses, obviously the rule addresses prescribing practitioners. Those would include doctors, dentists, veterinarians, but also mid level practitioners. We want to make it clear that nurse practitioners, advanced practice nurses, physician assistants, they can use this rule just as much as doctors and dentists and others can use it.

On the pharmacy side, as with the practitioner side, any DEA registered pharmacy can use this rule. For both of these entities, they have to select the application that they want to use, and that application has to meet DEA's requirements. For the practitioners, they have to undergo identity proofing, NSAID access controls, and sign the prescriptions, and we'll be touching on all these requirements as I continue. On the pharmacy side, obviously the key is selecting an application that meets our requirements, and then there are some implementation aspects as well.

For application providers, and I want to emphasize here that for DEA's perspective, application providers includes EHRs, e-prescribing applications, and pharmacy applications. So the entities that provide those pharmacy applications are just as affected by this rule as those on the EHR side. Those application providers, we recognize are going to have to evaluate their applications, and see what changes they may need to make to comply with this rule. And then once they've made those changes, we want to make sure that they've made those changes in a way that addresses our requirements. And so we're requiring

that the application providers undergo some form of third party audit or certification, and I'll be touching on those requirements at the end of the presentation.

Addressing the practitioner requirements to begin with, we want to make sure that people who have the authority to prescribe controlled substances are able to do so, and we also want to make sure that people who don't have the authority to prescribe controlled substances aren't able to do so. Obviously DEA's mission is specific to preventing and deterring the diversion of controlled substances into elicit markets, and that can happen in a number of ways, both from insider threats and from outsider threats. And so our goal is to address both of those.

We've done that first by requiring that individual practitioners undergo identity proofing, and so this is really just to make sure that the person who indicates that they want to conduct this activity is who they claim to be. DEA is requiring that the identity proofing be conducted by a credentialed service provider or a certification authority that is licensed or approved by the federal government in some fashion and that that identity proofing has to comply with identity proofing under NIST 80063-1 Level 3, so one of the key elements of allowing Level 3 is that we now permit identity proofing to be conducted either in person or remotely. We want to make sure that this rule is as accessible to as many people as possible, and we believe that allowing remote identity proofing is a key element in that.

Once the identity proofing has been successfully conducted, the credential service provider or the certification authority will issue a two-factor authentication credential. I'll be touching on that in a moment. We recognize that the pathway that I've just outlined addresses individual practitioners. And institutional practitioners such a hospitals and clinics, they go through their own credentialing process internally just to allow someone to practice at their facilities. So in the rule, we've allowed institutional practitioners like hospitals to either conduct their own identity proofing based on their credentialing authorities and work that they've already done, or they can use the same methods that are allowed for individual practitioners.

In terms of how this is going to work ultimately, we don't expect any individual practitioner to have to figure out what entities are approved by the government. Where should I go to? I want to do this. We expect that the application providers themselves will partner up with a credential service provider or a certification authority that's already out there, already in business, already doing this as part of their normal business operations, and then that application provider will turn around and tell its practitioner users, I've partnered with this entity. Go to them. Get your identity proofing done. Here's what you need to do.

We hope that this will be very seamless. We expect these partnerships will work well, and we certainly don't anticipate that individual practitioners will have to go searching for entities to conduct their identity proofing for them. We expect the application providers to let their users know where they should go to undergo this.

Moving to the next slide on two-factor authentication credentials, as I've noted, DEA is an entity that is concerned about making sure that only persons who have the proper authority to prescribe controlled substances can do so. In an electronic arena, we believe that this is best accomplished through two-factor authentication. We really believe that this is important, not just from our perspective, but it's really important from the practitioner's perspective too. We want to make sure that that practitioner can't be taken advantage of. We want to make sure that that doctor doesn't have a staff member or an outsider who uses that doctor's identity and authority illicitly to prescribe controlled substances. We also believe it helps with the possibility of hacking or other types of things, so we're really looking at this not just from our own needs, but as a way of really protecting that practitioner from threats that he may not be even aware of.

And our concern is that not requiring two-factor credentials and just relying on passwords. Passwords are pretty vulnerable. They're easily guessed. If I don't want it to be a difficult password, I'm going to make it something that I'm going to remember. If I remember, there's a pretty good possibility that my own staff, if I'm a practitioner, is going to know that my favorite baseball team is the Nationals or my favorite football team or whatnot. So we want to make sure that there isn't that vulnerability from passwords, either by being guessed or by being written down because we're all human. And if we can't remember it, we write it down, and we probably post it on our workstation. And we want to make sure that just doesn't happen.

What we're requiring is the use of two-factor credentials. Any two out of the three elements can be used, so you can either use a password and a hard token of some sort, a password and a biometric of some sort, or a biometric and a hard token. It's up to the application provider as to how they choose to implement that. Obviously we figured that they'll work with their practitioners to let them know what's acceptable, and they'll work with the credential service providers and the certification authorities to make sure that those CSPs or CAs are issuing the right types of credentials.

The really key element of this whole concept is the last bullet on this slide. What I want you to take away from all of this is that, from DEA's perspective, there are only two times that that authentication credential has to be used. One is on a limited basis, and that's when access controls are either set or changed, and I'm going to touch on what those are and when they're used in just a moment. The other time is when a controlled substance prescription is actually signed. Those are the only times that the authentication credential needs to be used.

I want to make it clear that DEA's rule does not require that the credential be used to access the computer as a whole. We don't require that it be used to access the EHR or the e-prescribing application as a whole. We don't require that it be used to access a particular patient record as a whole. The only times that we require it be used is to approve access controls and to sign controlled substance prescriptions.

On that note, what are access controls, and why are they part of this system? Access controls are designed to make sure that the permission to approve and sign controlled substance prescriptions is only granted to persons who have the authority to do so. So in an office setting, one person designated by a practitioner will make sure that persons who are being granted permission to sign controlled substance prescriptions have the state authorization and the federal authorization to do so. And then a second person who is a DEA registrant, and who has that two-factor authentication credential will approve the granting of access to sign controlled substance prescriptions.

For many practices, this isn't going to happen very often. It's going to happen when you first initialize your system to sign controlled substance prescriptions. And it will happen whenever there is turnover, so if you don't have much turnover at your practice, you won't need to do this very much. In a larger practice, when we're setting LIFA, it may need to happen more frequently. And in institutions, the concept is the same, but how it's implemented is a little bit different. We envision that it be implemented by two separate offices within the hospital or clinic. But that's just to make sure that one person on their own can't grant someone the authority to sign these prescriptions when that person doesn't have it. So it's allowing for some checks and balances.

Moving to how controlled substance prescriptions are signed, as with paper prescriptions, an agent or the practitioner can enter the prescription information into the system and prepare it for the practitioner's signature, so that's just the same as it is with paper prescriptions today, and that type of activity is still

permitted. Once a practitioner decides that they're ready to sign those prescriptions, they're going to access a list of controlled substance prescriptions on what we refer to as a review screen, and those prescriptions are all for one single patient. The list can obviously include prescriptions for non-controlled substances, so if you're treating a patient, and you've got two non-controlled substances, and one controlled substance, the list can show everything. What's required for DEA's rule just relates to controlled substance prescriptions.

Once that list is up and present, you can see here the information that's required to be present. It's basically all of the information that's required on a controlled substance prescription today, so date of issuance, the patient name, all of the drug information, and all of the information about the prescribing practitioner. The one thing I do want to note is based on comments that we received through the NPRM. The patient address is not required to be shown on this screen. It is, however, required to be part of the prescription and is required to be transmitted and signed. So that doesn't have to appear on this screen. We recognize that that's not something that you look to.

On the next slide, while all of that information is shown, there needs to be a statement on the screen that indicates that completing the two-factor authentication protocol is legally signing the prescription and authorizing that prescription to be sent to the pharmacy for dispensing. This statement must be displayed, but it does not require any action on the part of the practitioner. So there's no checkbox. There's no okay button. It's just present on the screen.

The practitioner has to indicate every controlled substance prescription that is ready to be signed. We don't specify how that occurs. It's possible it could be a checkbox or some other method. I do want to make it clear though that there does need to be an action on the part of the practitioner to actively indicate that something is ready to be signed versus having everything check-marked and then having to actively go out and uncheck the things that you don't want to be signed. So it does need to be an active act on the part of the prescriber to indicate those prescriptions that need to be signed.

Once that indication has occurred, the practitioner would be prompted to complete the two-factor authentication protocol using the credential that we just talked about, and again, to emphasize this is the time when you're going to use that credential. It doesn't get used for accessing any other part of the records or accessing the computer as a whole. When that credential is used, either the application itself will digitally sign the DEA elements, or if they practitioner obtain their own digital certificate as part of their identity proofing, that practitioner's digital certificate will digitally sign the DEA elements. And once those have been digitally signed, they cannot be altered. But what this allows is once those elements have been signed, other information can be added to the prescription after that, so information such as pharmacy information, other routing information, information about a patient's location, information about insurance. All of that can be added after those DEA elements have been signed.

Moving to the next slide, you'll see the first elements on the next slide is because those DEA elements have been digitally signed, there's no need for immediate transmission. We want to make sure that we don't interrupt workflow, so all that other information can be added before the prescription is transmitted to the pharmacy.

We recognize that electronic prescriptions are definitely a step forward, and they're definitely very useful, but there are times when information from those prescriptions needs to be printed, either because the patient asks for a copy of the prescription just for their own records, so we permit that, so long as that printed document indicates that it's a copy, and it's not intended as a valid prescription for dispensing. We also recognize that information needs to be able to be transferred into medical records or into other lists, and that is definitely permissible within this rule.

Finally, although we all would like for electronic prescriptions to always go through seamlessly, we do recognize that sometimes transmissions aren't successful. And so there may be a need where a practitioner is notified that a transmission wasn't successful. In those instances, the practitioner can print the prescription that was already transmitted and manually sign it, but the prescription has to specifically indicate that it was previously transmitted electronically and the name of the pharmacy that it was transmitted to and the date and time of transmission. We want to be very certain that there's no opportunity for double dispensing at the pharmacy end.

Finally, I'd like to emphasize on this slide that all electronic prescriptions for controlled substances, once they're transmitted, must remain electronic throughout. They cannot be converted to facsimile during transmission, so once electronic, always electronic.

Moving to the pharmacy requirements, I think this is an element that sometimes is a little bit overlooked. From DEA's perspective, electronic prescribing of controlled substances involves two registrant entities, the prescriber and the pharmacy. So the pharmacy needs to select a pharmacy application that meets DEA's requirements. Once they've done that, they need to set access controls to insure that only authorized persons at the pharmacy can annotate or alter a prescription where permissible to make sure that only those people at the pharmacy who have the authority do to that can do that.

As I noted, pharmacies are permitted to receive those electronic prescriptions for controlled substances. All of those records must be archived electronically. All the annotations must be made electronically, and all of the records must be kept electronically. So we really are looking forward to the ability for all of this to be end-to-end electronic.

Looking at something that we all hope doesn't happen, but we recognize is a possibility, we do recognize that there could be the potential for security incidents within this system, so we require that electronic prescription or health record applications that are conducting e-prescribing activities and pharmacy applications must conduct internal audits on a daily basis to determine whether a security incident has occurred. Those audits look at a number of different elements, and that internal audit look is completely automated.

That audit review generates a report for human review, so when we look at what might be a security incident, we would be looking for things like prescriptions that were assigned by someone who didn't have the authority to do so, or that were annotated by someone who didn't have the authority to do so or that were altered after signature, things like that. If a security incident has occurred, then DEA needs to be alerted, and the application provider needs to be alerted because there's a possibility that there could be some application issues that may need to be looked at and corrected.

How does this all affect applications? When an application provider looks at the requirements the DEA is imposing in this rule, there are a number of different elements that are summarized here. Both pharmacy and practitioner applications, meaning EHR applications and e-prescribing applications, have to allow the setting or changing of access controls like we talked about to make sure that only people who have the authority to do certain activities are allowed to do those.

On the electronic prescription side, the application has to permit the use of two-factor authentication credentials for signing the prescriptions and for approving the access controls. Both the application providers on the practitioner and the pharmacy side need to have audit trails, as we just touched on. On the practitioner side, there needs to be some digital signature of those DEA elements, whether it's by the

prescription application itself or by the individual practitioner if that individual has obtained their own digital certificate. And the DEA information all needs to be included in that prescription.

On the pharmacy side, we need to make sure that all the information that's required on that prescription needs to be able to be imported and displayed and stored. We don't want anything to get lost in transmission. We don't want anything to get lost at the pharmacy. Finally, as we've touched on, there needs to be some records for all of those controlled substances.

Looking at how an application provider is supposed to know whether they meet all of these requirements, we recognize that it would be very difficult for an individual practitioner or a pharmacy to know on their own, independently, whether an application meets DEA's requirements, and to make sure that practitioners and pharmacies get good information about those requirements. We require that application providers undergo third party audits of their application. They need to undergo one out of these three, so it can either be conducted by an independent certification organization the DEA has approved, or it can be conducted by a certified information system's auditor, or it can be conducted by an entity that conducts Web trust, CIST trust, or SAS 70 audits. So we really have tried to be flexible in this area to allow as many different possibilities for these third party audits or certifications as possible.

We want to make sure though that there is that third party check to make sure that these applications are doing what they are supposed to be doing and what they may very well claim that they do. And so these audits need to actually do that. They need to make sure that the application does comply with DEA's requirements. When they do that, they need to issue a report to the application provider, and then that application provider needs to make that audit or certification report available to any practitioner or pharmacy that either uses the application currently or is considering use of the application. Ultimately, it's the responsibility of that DEA registrant, the pharmacy, or the practitioner to look at that report and make sure that the system or the application that they're selecting complies with DEA's requirements.

That's a brief overview of our rule. Again, we appreciate the opportunity to be here today, and I'm happy to answer any questions that you may have.

John Halamka – Harvard Medical School – Chief Information Officer

This may be something beyond the scope of your ability to answer the question, but many of my clinicians have said, might my cell phone be considered a hard token? That is to say, my Blackberry is cryptographic end-to-end between the server and the device. It is a token, a hardware device, which I could uniquely register to me through one of your organizations that would do that kind of identity proofing, and imagine that something that I know, a user name and password, is typed in, as I sign for the controlled substance. Something that I have, my cell phone, after I sign, receives a code via an encrypted message, which then I would type in, in the same way that I would do it from a hard token like an RSA secure ID. The only reason I ask is because clinician acceptance of carrying this is very high. Clinician acceptance of carrying a secure ID type token is very low.

Michelle Ferritto – DEA – Acting Administrator

Sure. It would depend on whether the application on the cell phone met the requirements that DEA has included for a hard token, and so those have to do with several different federal information processing standard requirements, so in certain instances, the answer to your question is yes, and in other instances, the answer to your question may be no. But there is definitely that possibility.

There's a definite conception, and DEA certainly believes a misconception out there that two-factor authentication is very challenging. Ultimately when you look at it, it's not that much more difficult than

going to your ATM. When we go to an ATM, and we want to withdraw cash, we don't just put in our pin. We also insert our ATM card.

John Halamka – Harvard Medical School – Chief Information Officer
That's true.

Michelle Ferritto – DEA – Acting Administrator
And we would probably be awfully uncomfortable if anybody could walk up to an ATM and punch in a four-digit code, and money spit out, but you didn't really know where it came from.

John Halamka – Harvard Medical School – Chief Information Officer
Sounds good.

Michelle Ferritto – DEA – Acting Administrator
Sounds good unless it's your account and you didn't get the money. And that's our same concern on electronic prescribing of controlled substances, so it's a little bit longer answer to your question, but the answer to your question is, it depends on how that cell phone is configured and whether it meets the FIPS standards that DEA has provided in the rule.

John Halamka – Harvard Medical School – Chief Information Officer
Sure. I understand. Every one of our workflows is going to have a different type of two-factor authentication. Our emergency physicians are in a constrained space using 20 PCs and it's, say, 20 clinicians, and they love biometrics, very easy to deploy into a controlled space. I have 2 million square feet and 8,000 devices, so putting biometric readers on 8,000 devices is harder. So hence there the use of some type of mobile device, whether it is a FIPS compliance cell phone or a token or some other type of two-factor authentication would be used. Other questions?

Michelle Ferritto – DEA – Acting Administrator
Just to add onto your thought, we have worked very hard in this rule recognizing that there are a lot of different implementation potentials, and we really did want to be as flexible as we possibly could to allow whatever would work within our concerns to work for you and to deal with the workflow issues. So we have tried very hard to be as flexible as we can.

John Halamka – Harvard Medical School – Chief Information Officer
Great. I would assume that Dixie would have some thoughts, and that Kevin would have some thoughts. Not Kevin, it's John.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I'm not going to ….

John Halamka – Harvard Medical School – Chief Information Officer
Okay. He's just smiling so much. Dixie, please go ahead.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
You know, NIST special publication 800-63 is a really good document. Jodi, you'll remember, we wanted to cite that as our standard for authentication, level two being the floor for authentication, and we were told that we couldn't do that because you can't impose a federal standard on private industry. Why is it that we can do it; that DEA, it may be DEA is a special case or something, but why can we do it in this case, and we were told to take it out of our recommendations when we included it?

Jodi Daniel – ONC – Director Office of Policy & Research
There isn't. I'm not sure exactly what you were told or by who. There isn't a prohibition on relying on the federal standard and using that and imposing it on the private sector, at least that I'm aware of. I think there were other issues with respect to ….

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
No, this is exactly. Yes, I can go back and show you the spreadsheet where we wanted to recommend FIPS or NIST special publication 800-63 Level II authentication, and we were told we had to take that out because we couldn't impose it on private industry, so we did. And then we went through a step where we tried to reword it and put them in the recommendations, and that went out as well. So I'm glad to see that you were able to get that in your regulation because it is a very good publication.

John Halamka – Harvard Medical School – Chief Information Officer
I think it would be worthwhile, Dixie, for you and Jodi to close the loop and try to ….

Jodi Daniel – ONC – Director Office of Policy & Research
Yes. Let's do that. I'd like to ….

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. This is what I e-mailed you about, Jodi.

Jodi Daniel – ONC – Director Office of Policy & Research
Great. Let's talk …. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer
Great. Nancy?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I have 100,000 practitioners who are happy to see that this has moved along in this world. In the DoD, we've dealt with that a long time because many of our practitioners often – they also often move across state lines, and licensure and longitudinal prescriptions and advising of telemedicine has been an issue too.

I have one question, partly out of ignorance. Does the broader use case for electronic prescriptions cover the issue of the doctor sending it to that pharmacy, and the pharmacy doesn't have that substance in stock? Is there an electronic acknowledgement that comes back? I thought I saw something in a blog from a physician last week that said she had used her Epic System to send a script, and it turns out that the pharmacy she sent the script to didn't have that drug in stock, and she had no acknowledgement, and she thought it was a patient safety issue. So for me, it would certainly be an issue of, is the full set of specifications include an acknowledgement, yes, I've received your controlled substance prescription or any prescription, and we will stock that. Or, no, we do not supply this drug at this pharmacy. Please cancel this order and order another place.

John Halamka – Harvard Medical School – Chief Information Officer
Michelle, I think Kevin could answer that for you if that would be helpful.

Michelle Ferritto – DEA – Acting Administrator
Sure. Just briefly from DEA's perspective, it doesn't, but we certainly recognize that the industry is working towards some of those messaging issues.

Kevin Hutchinson – Prematics, Inc. – CEO
There are two elements that happen throughout the transmission, as the handoff occurs at each spot. From the application vendor to the network, from the network to the pharmacy, there is a handshake that says I got it. It moves to the next stage. I got it, all the way down to the store level that says I got it. So you see the handoffs that occur from the software to the network to the pharmacy data center in the case of a large chain, now all the way down to the store level. That just says it's gone through.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
That's an acknowledgement that I received your transmission.

Kevin Hutchinson – Prematics, Inc. – CEO
That's right. Then there is, as part of the NCPDP standard, there is another segment type that actually can do a validation all the way back that says we have the order, versus just that the transmission actually made it through its steps that we have actually the order. What is not there, I think, specific to your question is—

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Not in stock.

Kevin Hutchinson – Prematics, Inc. – CEO
There's nothing in there about whether it's in stock, out of stock, in inventory, out of inventory. Typically what the pharmacies will do is if they are out of stock, depending upon their configuration of their chain, is they will find ways to fill that prescription in another way through another store or through some other means. But that answer varies by hospital pharmacy, chain pharmacy.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Good, but I would … that this doctor said that was a potential patient safety issue if there was a delay or not depending on whether a doctor would prefer to say I've sent it to this pharmacy, and I can have it in 24 hours, or I can have it in three business days. Particularly for people who have very specialized meds like chronic conditions, I'd say that spec might be looked at to be matured and flushed out, just like the supply chain model is very good. I mean, if you go on Amazon, and there are 24 vendors offering you a book, the ones will tell you not in stock, and go try another one.

Kevin Hutchinson – Prematics, Inc. – CEO
Yes.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I think physicians may want that.

Kevin Hutchinson – Prematics, Inc. – CEO
Agreed.

Michelle Ferritto – DEA – Acting Administrator
Just a brief comment as a follow up, as with written prescriptions, nothing in this rule from DEA's perspective prohibits the transfer of that unfilled prescription from one pharmacy to another. While it doesn't address your specific concern, please recognize that nothing in this rule would prohibit the patient from receiving the medicine, just perhaps not at the first pharmacy.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
That's tricky.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I've got three questions too, which are easy. First, I want to say to you, Michelle and Jodi, and everyone else who worked on this, this is one of the most nuance and, therefore, possibly useful regulations I've ever seen, so I think the collaboration really deserves a lot of recognition. My first question is, in your summary today, you didn't talk about requirements on the network that exchanges the information between the pharmacy and the e-prescribing application. Are there requirements in the regulation for that? Is there an audit requirement for the network and so forth?

Michelle Ferritto – DEA – Acting Administrator
Not from DEA's perspective. The only requirement that's immediately apparent is the prescription has to remain in its electronic form from end-to-end. We recognize that right now some networks start out with an electronic prescription, and it gets part way through, and someone along the way said, oops, that can't be sent to the pharmacy. I'm going to turn it into a fax. And that would invalidate the prescription and make it not legal, so that would be the one key element that immediately addresses your question. But … we looked to HHS….

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So the digital signature of that portion of the transaction actually gives you the security that you need to prevent diversion without having to go and certify the network and so forth. I think that's great. The process of auditing an electronic health record application that has e-prescribing, you can look at the challenge of making sure that no prescription escapes that thing without having been signed as requiring a review of the signing screens, a review of the system administration screens, and that's about it. Or you could look at a need for a full, in-depth review of all of the code in the system to assure that there isn't some unauthorized patch that could be entered by someone. What is the level of audit that you expect in terms of fulfilling the regulation?

Michelle Ferritto – DEA – Acting Administrator
I think the audit slide or the application provider slide talked about the types of audits and certifications that we're requiring, and it would depend on the application and whether it was an installed application. But we're looking for the audit or the certification to demonstrate compliance by the application with DEA's regulations, including security and integrity of the application. And the regulatory text provides you with the specifics that we're looking for from those audit or certifications.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Has this process been conducted at all so far? Will it start after the rule is in place? Are there EHRs that have met these audits yet?

Michelle Ferritto – DEA – Acting Administrator
The rule is just out.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I know.

Michelle Ferritto – DEA – Acting Administrator
And it hasn't become effective yet. What we've tried to do here is to allow a number of commercial entities to conduct audits based on the regulatory requirements, so any company that already conducts Web trust, CIST trust, or SAS 70 audits could offer its services to audit for these regulations. The same would be true for any certified information systems auditor who conducts those types of activities as a daily part of their business. And then obviously the third component is DEA looks forward to receiving

interest from entities that want to be approved by DEA as independent certification organizations. I think the regulations are so new that no one has yet been audited as meeting them. I mean, recognizing they've been out for about a month.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer
Kevin, John, and….

Kevin Hutchinson – Prematics, Inc. – CEO
…last. I'll wrap up.

John Halamka – Harvard Medical School – Chief Information Officer
Okay, so John, David, and then Kevin the last word, and then we'll do public comment.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
My name is John Derr. I represent long-term care and post-acute care. We really do support e-prescribing and that, and we're wondering whether you're going to be a little bit more flexible, speaking about workflow and all patients and that. We're a little bit different, especially in nursing homes. It's a three-way communication between a prescriber, the pharmacy, and the nursing facility where the nurse is actually the lynchpin that's in here. And, historically, the DEA has not recognized the nurse as a prescriber or nurse as an agent.

And so the question is, and I have a long letter that I'm submitting to Judy to help you out, is would the DEA consider the nurse as an agent because we've been working with NCPDP and all the standards and the workflow of a nursing home with this three-way communication. And we have to redo a lot of standard work. We'd have to redo – the software vendors would have to do a lot of work only because the workflow, which you've talked about, is not recognized because it was developed, what we can see, as an ambulatory or an office practice workflow model and now one that would address nursing homes.

Michelle Ferritto – DEA – Acting Administrator
Sure. Just to reemphasize the requirements of existing regulations for DEA that are addressed in this rule, prescriptions for controlled substances must be signed by DEA registered practitioners, so we certainly….

John Derr – Golden Living LLC – Chief Technology Strategic Officer
I've always been afraid of, when I've looked at e-prescribing years ago, that we'd end up in a doctor's office with two different systems, and it's hard enough sometimes to get somebody on one system, and so I would urge again. Whatever you have to do, and I'm not that familiar with it, to be able to include our nurse in this process as a licensed agent.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
You mentioned in the audit requirements or audit of the system. Is there an additional requirement for audit of the usage of the system with respect to, for example, all of the controlled substances written by a particular practitioner or all of the controlled substances for a particular patient? Is that a requirement of the rules also?

Michelle Ferritto – DEA – Acting Administrator

There is a requirement in the rule for the application provider to make available to the prescriber a list of all controlled substances that the prescriber – all controlled substance prescriptions that the prescriber wrote during a calendar month, and that must be made available seven days after the end of the month. In terms of an outside audit of those prescriptions, no, there's no requirement. There must also be an ability on the part of the prescriber to access a list of all of his or her prescriptions for controlled substances written during at least the last two years and to be able to sort those. So if someone wanted to go back and look at their own prescribing history, they could do that.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Thank you.

John Halamka – Harvard Medical School – Chief Information Officer
Kevin, the last word.

Kevin Hutchinson – Prematics, Inc. – CEO
On the auditors, the certified information systems auditors, and I know the independent certification organizations would still need to apply and then be approved, but when will we know who those organizations might be that we would, as an applications supplier, be able to get audited by to be approved?

Michelle Ferritto – DEA – Acting Administrator
Well, as I noted, Web Trust, CIST Trust, SAS 70, and … auditors are out there now, and they're currently marketing their business, so Web Trust, CIST Trust, and SAS 70 audits are available through large accounting type companies and such, as well as certified information system auditors. Specifically on the certification organizations, DEA would need to receive requests from organizations to be approved. As certification organizations, we'd need to look at how those entities planned to conduct their certifications. Once we approved a particular entity, we would publish something in the federal register indicating that XYZ Company has been approved to conduct, as a certification organization, for electronic prescriptions, for controlled substances, or pharmacy applications and post that on our Web site as well.

Kevin Hutchinson – Prematics, Inc. – CEO
Okay. You said that the application provider should be telling the physician that which credentialing authority they should be using for identity proofing.

Michelle Ferritto – DEA – Acting Administrator
Sure.

Kevin Hutchinson – Prematics, Inc. – CEO
So I could imagine a world where there's a lot of alignment happening. Why is the application provider telling the physician versus the physician, simply through their normal credentialing that they do, the organization that they might use for that credentialing? Is there something that they receive after identity proofing that we know that they have actually fulfilled that process?

Michelle Ferritto – DEA – Acting Administrator
Yes. The reason that the application provider needs to align itself with a credential service provider or a certification authority is because after the identity proofing is conducted, that credential service provider or certification authority either issues the two-factor credential to the practitioner or enables an existing credential to be used for electronic prescribing of controlled substances. So the application provider is going to itself need to decide what types of credentials it wants to code for and then figure out who to work with that can issue those credentials.

Kevin Hutchinson – Prematics, Inc. – CEO
And those are also certified by the DEA, those CAs and CSPs?

Michelle Ferritto – DEA – Acting Administrator
No. The credential service providers are approved by the General Services Administration, and there's a list on GSA's Web site. And the certification authorities are certified by the federal bridge certification authority, and there's a list of those certification authorities that would meet NIST Level 3 identity proofing on FBCA's Web site.

Kevin Hutchinson – Prematics, Inc. – CEO
Last, and this is more of a comment. After Wes' question, I have a little bit more clarity too, but I'd love to hear some commentary on, if a prescription has gone through a two-factor authentication, and let's say that a store loses connectivity to its network for whatever reason, which does happen from time-to-time. They go down for 30 minutes, let's say, or an hour, where they've lost connectivity. Why is it that that prescription, after being authenticated, and after going through two-factor, could not be delivered by fax at that point? Or if you've got an independent pharmacy who is not connected to the network, and it goes through the system, and it is a two-factor authentication and all of that has occurred, it's digitally signed, because it is legal to fax controlled substances for Schedule III through V.

Michelle Ferritto – DEA – Acting Administrator
It is legal to fax written and manually signed prescriptions for Schedule III, IV, and V controlled substances. Electronic prescriptions will not provide that same type of manual, physical signature for the pharmacy to know that it's been signed by the DEA registrant. Instead, there are other electronic means that the rules envisions for that pharmacy to know, and to know that the prescription has been signed in a manner that meets DEA's requirements. To turn that into an unsigned facsimile invalidates the prescription.

Kevin Hutchinson – Prematics, Inc. – CEO
That would imply that a two-factor digital sign is not a stringent signature.

Michelle Ferritto – DEA – Acting Administrator
No, I don't agree with you there. I think there are just, when it comes to the signature requirements, there are some requirements for electronic prescriptions, and then on the paper prescription side, there are requirements for paper prescriptions.

Kevin Hutchinson – Prematics, Inc. – CEO
I think that's going to be a little bit disruptive in the process because these things are going to happen in the network, and to be able to send those when those disruptions occur, and it is a two-factor signed, digitally signed prescription. I understand that it's not something you want to do commonplace, and it should only happen when there's been a loss of connectivity or something else that has occurred. But I think that it's going to create issues with the physician to send it back to say this did not go through. They have to print it. They have to sign it, and they're going to fax it to the exact same fax machine that the order couldn't be faxed to in the first place. But I understand this could have a manual signature on it now and not a digitally signed signature.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks very, very much, Michelle and Jodi. I think this was a very, very rich discussion. You can tell by the level of interest, this is something we've all been looking for, for a very long time.

Kevin Hutchinson – Prematics, Inc. – CEO
By the way, the Q&A is excellent. That document that you have on the Q&A that outlines all the things of what questions to consider—sorry to interrupt—it's a fabulous document. Great job with that.

Jodi Daniel – ONC – Director Office of Policy & Research
I'll just put in a public service announcement that this is still open. There's an interim final rule, so if folks have public comment, there's an opportunity to do that.

Michelle Ferritto – DEA – Acting Administrator
Thank you very much for inviting us today.

John Halamka – Harvard Medical School – Chief Information Officer
Thank you. John P., public comments, and then….

Jonathan Perlin – Hospital Corporation of America – CMO & President
Yes. I think … really rich discussion. Thank you for great progress in the digital signature for controlled substances. Judy?

Judy Sparrow – Office of the National Coordinator – Executive Director
…public comment portion of the meeting. Anybody in the audience who cares to make a comment, please step up to the mic. Anybody on the telephone … press star, one, and anybody on the Web, please dial 1-877-705-6006. Please remember to state your name, your organization, and there is a three-minute time limit. Bill?

Bill Briefwaite – Anicam – CMO
Hello. I'm Bill Briefwaite. I'm a retired physician. I used to prescribe, but not electronically. I'm also the chief medical officer of a company called Anicam. First I want to say that the Internet production works really well. I spent the money on the Internet listening to this, and it works really well. Thank you for doing that. Secondly, I'd like to applaud the DEA and ONC for the publication of this long awaited rule. Adopting this Level 3 assurance for authentication specifically makes a lot of sense to me.

However, an extension of John's comment and question, the DEA seems to have judged the use of out of band tokens as not acceptable only because the DEA "doubts" that they're practical because they require more time for each authentication. This is not a security issue, and I think the DEA should let the market decide whether that sort of technology can be timely or not. Unless there is some unspoken security flaw in the use of out of band tokens, and when they're used appropriately, I think that the DEA should clarify in a technical correction before the June 1st date so that people don't worry about this and go to other technologies. They should adopt the NIST definition of out of band tokens, and make it clear that those are acceptable alternatives.

If this correct is not made, I believe the final rule will serve as a barrier to physician acceptance because it's less flexible, less easy for them to use, and it's more expensive to use hard tokens, so I would suggest a change, and obviously I'll be putting that comment in as a comment as well. But since the comments aren't due until June 1st, and it is a final rule on June 1st, perhaps a technical correction would be a better way to prevent this becoming a barrier. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks for coming.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. We do have a caller on the phone. Could you please identify yourself?

Operator
Our next question is from Peter Kaufman with DrFirst Corporation.

Peter Kaufman – DrFirst – Chief Medical Officer
Hello. This is Peter Kaufman. I have a couple comments and an important question. The comment is in regards to the … the reasons you can't use a Blackberry as your sole device is that the rule clearly states that the hard token needs to be on a separate device from the computer. You could use a Blackberry as your hard token potentially, but then you'd have to be e-prescribing on another device.

The second factor is that the physicians in our trial in Western Massachusetts who are using hard tokens all expressed concerns about the hard tokens before the study, but now that they're actually prescribing with the hard tokens, they don't find it an issue at all. Zero of them have had complaints about the hard token in actual use, and we have 79 users up and running. Not all of them have written prescriptions, but the majority of them have.

The question I have has to do with sending prescriptions while waiting for NCPDP to go through the process that will take almost two years to generate a DUF, get the DUF approved, and have that version of script approved by CMS to have a field in which to send a flag that the prescription was signed electronically. Is DEA working on a temporary solution that they mail out for 24 months or 18 months to have some sort of an envelope and a secondary passage to the pharmacy or some other way of sending a message through? Otherwise, other than using PKI, who … structure does not exist, how are we going to be using this system starting anywhere close to June 1, 2010?

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Next caller on the phone?

Operator
Our next caller is Brian Ahier with healthcare for the mid Columbia region.

Brian Ahier – Mid-Columbia Medical Center – Health IT Evangelist
Good afternoon, and thank you for the great presentation today. I think this is an excellent ability to be able to prescribe narcotics, and I congratulate DEA and ONC on getting this interim final rule published.

My question may be outside the scope of the standards committee, but I wanted to make sure that we got this question posted, and maybe Jodi can carry this back to the ONC. It's really regarding the definition of meaningful use and the percentage of eligible or permissible prescriptions that you're going to be required to e-prescribe now that this rule becomes final, will narcotics be considered when you factor that equation. The reason why this is important is because, while many providers are going to be very glad, ultimately, of the ability to e-prescribe controlled drugs, if someone is already on their way down the path towards meaningful use, and they're currently e-prescribing, they may not be quite ready for the dual-factor authentication to e-prescribe narcotics, and so this may increase the percentage drugs that are not currently being e-prescribed. Thank you very much.

Jodi Daniel – ONC – Director Office of Policy & Research
Thank you for that. It is something that's on our radar screen, and I appreciate the comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. We have one final caller on the phone.

Operator
Our next question is from Shelly Spiro with Federal Consulting Incorporated.

Shelly Spiro – ASCP – President
Good afternoon. My name is Shelly Spiro. I'm very involved in the NCPDP work and also the work with the long-term care group, and I want to thank John Derr for bringing our questions forward on behalf of the American Society of Consultant Pharmacists.

One of the clarification questions that we are looking for, especially in the long-term and post-acure care environment is a question that we have not been able to figure out in the interim final rule, which is, if the physician uses a facility, a long-term care facility EHR that's part of their – the electronic prescribing is incorporated into the facility's EHR, if that facility is not a registrant themselves, can that physician actually enter the electronic prescription into that facility's EHR and then transmit it to the pharmacy and/or can that facility, long-term care facility act as an intermediary to be the one to transmit that prescription directly to the pharmacy? Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. A final comment in the room, Richard Singerman.

Richard Singerman – BioQuest – President
Hello. Richard Singerman, The Singerman Group. This is a comment about the horizon scan that was measured for the – that was discussed for the e-measures. And that is, the comment was made that folks want to look at e-measures from those top-performing organizations, both those measures that require workflow reengineering and those that don't.

And I would suggest this is a great opportunity to kind of maybe broaden that scan a little bit, granted you have limited resources, so that if organizations are seeing progress along certain e-measures, it would be helpful to have the context in which that progress was made. And by that I mean, is the organization a staff model? Is it a closed system like Kaiser and the VA? If it's a mixture of staff model and external physicians or non-staff, where were the improvements made, so that someone can see the whole value chain from a certain improvement was made according to an e-measure, but this was the context or environment in which it was made, and that'll actually tie into some of the implementation workgroup concerns about not one size fits all in terms of what are organizations really going to leverage in terms of their path to adoption.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. I'll turn it back to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I want to thank everyone for their diligence, a long day, very rich discussion, and great public input afterward. I appreciate that. I think we're beginning to see the fruits of labor with regs, such as we just heard, and create the context to move from theory to practice, and in fact test some of the parameters. I think that last discussion really identified how we'll test the practicalities of implementation. John, anything you want to throw in?

John Halamka – Harvard Medical School – Chief Information Officer
It was a very good day, and as Doug was walking out the door, he said, you know, I'm going to go with those ONC folks and get a whole list of marching orders and projects and priorities all with the new

framework, so I'm sure we'll have many things to do ahead. And on that note, I think we stand adjourned. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you.

Public Comment Received During the Meeting

1. Will you please clarify if the DEA allows a facility's EHR to be the originator of the electronic prescription if the facility is not owned or is a registrant or if the facility EHR can act as an intermediary…Clarification of previous question… will you please clarify if the DEA allows an LTC facility's EHR to be the originator of the electronic prescription if the LTC facility is not owned nor is a registrant or if the LTC facility EHR can act as an intermediary.